

Excluded methods. Refers to a variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods would include recombinant DNA, cell fusion, and micro- and macroencapsulation. Such methods would not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.

Feed. Edible materials which are consumed by livestock for their nutritional value. Feed may be concentrates (grains) or roughages (hay, silage, fodder). The term, "feed," encompasses all agricultural commodities, including pasture ingested by livestock for nutritional purposes.

Feed Additive. A substance or combination of substances added to feed in micro quantities to fulfill a specific nutritional need, i.e., nutrients in the form of amino acids, vitamins, and minerals.

Feed Supplement. A feed used with another feed to improve the nutrient balance or performance of the total ration and intended to be:

- (1) Diluted with other feeds when fed to livestock;
- (2) Offered free choice with other parts of the ration if separately available; or
- (3) Further diluted and mixed to produce a complete feed.

Fertilizer. A single or blended substance containing one or more recognized plant nutrient(s) which is used primarily for its plant nutrient content and which is designed for use or claimed to have value in promoting plant growth.

Field. An area of land identified as a discrete unit within a production operation.

Forage. Vegetable material in a fresh, dried, or ensiled state (pasture, hay, or silage) which is fed to livestock.

Handle. To sell, process, or package agricultural products, except such term shall not include the sale, transportation, or delivery of crops or livestock by the producer thereof to a handler.

Handler. Any person engaged in the business of handling agricultural products, including producers who handle crops or livestock of their own production, except such term shall not include final retailers of agricultural products that do not process agricultural products.

Handling operation. Any operation or portion of an operation (except final

retailers of agricultural products that do not process agricultural products) that receives or otherwise acquires agricultural products and processes, packages, or stores such products.

Immediate family. The spouse, minor children, or blood relatives who reside in the immediate household of a certifying agent or an employee, inspector, contractor, or other personnel of the certifying agent. For the purpose of this part, the interest of a spouse, minor child, or blood relative who is a resident of the immediate household of a certifying agent or an employee, inspector, contractor, or other personnel of the certifying agent shall be considered to be an interest of the certifying agent or an employee, inspector, contractor, or other personnel of the certifying agent.

Inert ingredient. Any substance (or group of substances with similar chemical structures if designated by the Environmental Protection Agency) other than an active ingredient which is intentionally included in any pesticide product used in organic crop or livestock production and handling (40 CFR 152.3(m)).

Information panel. That part of the label of a packaged product that is immediately contiguous to and to the right of the principal display panel as observed by an individual facing the principal display panel, unless another section of the label is designated as the information panel because of package size or other package attributes (e.g., irregular shape with one usable surface).

Ingredient. Any substance used in the preparation of an agricultural product that is still present in the final commercial product as consumed.

Ingredients statement. The list of ingredients contained in a product shown in their common and usual names in the descending order of predominance.

Inspector. Any person retained or used by a certifying agent to conduct inspections of certification applicants or certified production or handling operations.

Inspection. The act of examining and evaluating the production or handling operation of an applicant for certification or certified operation to determine compliance with the Act and the regulations in this part.

Label. A display of written, printed, or graphic material on the immediate container of an agricultural product or any such material affixed to any agricultural product or affixed to a bulk container containing an agricultural product, except for package liners or a display of written, printed, or graphic material which contains only

information about the weight of the product.

Labeling. All written, printed, or graphic material accompanying an agricultural product at any time or written, printed, or graphic material about the agricultural product displayed at retail stores about the product.

Livestock. Any cattle, sheep, goat, swine, poultry, or equine animals used for food or in the production of food, fiber, feed, or other agricultural-based consumer products; wild or domesticated game; or other nonplant life, except such term shall not include aquatic animals or bees for the production of food, fiber, feed, or other agricultural-based consumer products.

Lot. Any number of containers which contain an agricultural product of the same kind located in the same conveyance, warehouse, or packing house and which are available for inspection at the same time.

Market information. Any written, printed, audiovisual, or graphic information, including advertising, pamphlets, flyers, catalogues, posters, and signs, distributed, broadcasted, or made available outside of retail outlets that are used to assist in the sale or promotion of a product.

Mulch. Any material, such as wood chips, leaves, straw, paper, or plastic (on the National List), that serves to suppress weed growth, moderate soil temperature, or conserve soil moisture.

National List. A list of allowed and prohibited substances as provided for in section 6517 of the Act (7 U.S.C. 6517).

National Organic Program (NOP). The program authorized by the Act for the purpose of implementing its provisions.

National Organic Standards Board (NOSB). A Board established by the Secretary under 7 U.S.C. 6518 to assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of the National Organic Program.

Natural resources of the operation.

The physical, hydrological, and biological features of a production operation, including soil, water, wetlands, woodlands, and wildlife.

Nonagricultural substance. A substance that is not a product of agriculture, such as a mineral or a bacterial culture, that is used as an ingredient in an agricultural product. For the purposes of this part, a nonagricultural ingredient also includes any substance, such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product, so that the identity of the

agricultural product is unrecognizable in the extract, isolate, or fraction.

Nonsynthetic (natural). A substance that is derived from mineral, plant, or animal matter and does not undergo a synthetic process as defined in section 6502(21) of the Act (7 U.S.C. 6502(21)). For the purposes of this part, nonsynthetic is used as a synonym for natural as the term is used in the Act.

Nontoxic. Not known to cause any adverse physiological effects in animals, plants, humans, or the environment.

Nonretail container. Any container used for shipping or storage of an agricultural product that is not used in the retail display or sale of the product.

Organic. A labeling term that refers to an agricultural product produced in accordance with the Act and the regulations in this part.

Organic matter. The remains, residues, or waste products of any organism.

Organic system plan. A plan of management of an organic production or handling operation that has been agreed to by the producer or handler and the certifying agent and that includes written plans concerning all aspects of agricultural production or handling described in the Act and the regulations in subpart C of this part.

Peer review panel. A panel of individuals who have expertise in organic production and handling methods and certification procedures and who are appointed by the Administrator to assist in evaluating applicants for accreditation as certifying agents.

Person. An individual, group of individuals, contractor, corporation, association, organization, cooperative, or other entity.

Pesticide. Any substance which alone, in chemical combination, or in any formulation with one or more substances is defined as a pesticide in section 2(u) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136(u) *et seq.*).

Petition. A request to amend the National List that is submitted by any person in accordance with this part.

Planting stock. Any plant or plant tissue, including rhizomes, shoots, leaf or stem cuttings, roots, or tubers, used in plant production or propagation.

Practice standard. The guidelines and requirements through which a production or handling operation implements a required component of its production or handling organic system plan. A practice standard integrates a series of allowed and prohibited actions, materials, and conditions to establish a minimum level performance for planning, conducting, and maintaining

a function, such as livestock health care or facility pest management, essential to an organic operation.

Principal display panel. That part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for sale.

Private entity. Any domestic or foreign nongovernmental for-profit or not-for-profit organization providing certification services.

Processing. Cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, extracting, cutting, fermenting, eviscerating, preserving, dehydrating, freezing, or otherwise manufacturing and includes the packaging, canning, jarring, or otherwise enclosing food in a container.

Producer. A person who engages in the business of growing or producing food, fiber, feed, and other agricultural-based consumer products.

Production lot number/identifier. Identification of a product based on the production sequence of the product showing the date, time, and place of production used for quality control purposes.

Prohibited substance. A substance whose use in any aspect of organic production or handling is prohibited or not provided for in the Act or the regulations of this part.

Records. Any information in written, visual, or electronic form that documents the activities undertaken by a producer, handler, or certifying agent to comply with the Act and regulations in this part.

Residue testing. An official or validated analytical procedure that detects, identifies, and measures the presence of chemical substances, their metabolites, or degradations products in or on raw or processed agricultural products.

Responsibly connected. Any person who is a partner, officer, director, holder, manager, or owner of 10 percent or more of the voting stock of an applicant or a recipient of certification or accreditation.

Retail food establishment. A restaurant; delicatessen; bakery; grocery store; or any retail outlet with an in-store restaurant, delicatessen, bakery, salad bar, or other eat-in or carry-out service of processed or prepared raw and ready-to-eat-food.

Routine use of parasiticide. The regular, planned, or periodic use of parasiticides.

Secretary. The Secretary of Agriculture or a representative to whom authority has been delegated to act in the Secretary's stead.

Sewage sludge. A solid, semisolid, or liquid residue generated during the treatment of domestic sewage in a treatment works. Sewage sludge includes, but is not limited to: domestic septage; scum or solids removed in primary, secondary, or advanced wastewater treatment processes; and a material derived from sewage sludge. Sewage sludge does not include ash generated during the firing of sewage sludge in a sewage sludge incinerator or grit and screenings generated during preliminary treatment of domestic sewage in a treatment works.

Slaughter stock. Any animal that is intended to be slaughtered for consumption by humans or other animals.

Soil and water quality. Observable indicators of the physical, chemical, or biological condition of soil and water, including the presence of environmental contaminants.

State. Any of the several States of the United States of America, its territories, the District of Columbia, and the Commonwealth of Puerto Rico.

State certifying agent. A certifying agent accredited by the Secretary under the National Organic Program and operated by the State for the purposes of certifying organic production and handling operations in the State.

State entity. Any domestic, tribal government, or foreign governmental subdivision providing certification services.

State organic certification program. A State program that meets the requirements of section 6506 of the Act, is approved by the Secretary, and is designed to ensure that a product that is sold or labeled as organically produced under the Act is produced and handled using organic methods.

State program's governing State official. The chief executive official of a State or, in the case of a State that provides for the statewide election of an official to be responsible solely for the administration of the agricultural operations of the State, such official, who administers a State organic certification program.

Synthetic. A substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes.

System of organic production and handling. A system that is designed to produce agricultural products by the use of methods and substances that maintain the integrity of organic

agricultural products until they reach the consumer. This is accomplished by using, where possible, cultural, biological, and mechanical methods, as opposed to using substances, to fulfill any specific function within the system so as to: Maintain long-term soil fertility; increase soil biological activity; ensure effective pest management; recycle wastes to return nutrients to the land; provide attentive care for farm animals; and handle the agricultural products without the use of extraneous synthetic additives or processing in accordance with the Act and regulations in this part.

Transplant. A seedling which has been removed from its original place of production, transported, and replanted.

Tolerance. The maximum legal level of a pesticide residue in or on a raw or processed agricultural commodity as set by the Environmental Protection Agency under FFDCA, Section 408.

Unavoidable residual environmental contamination (UREC). Background levels of naturally occurring or synthetic chemicals that are present in the soil or present in organically produced agricultural products that are below established tolerances.

Wild crop. Any plant or portion of a plant that is collected or harvested from an area of land that is not maintained under cultivation or other agricultural management.

Subpart B—Applicability

§ 205.100 What has to be certified.

(a) Except for operations exempt or excluded in § 205.101, each production or handling operation or specified portion of a production or handling operation that produces or handles crops, livestock, livestock products, or other agricultural products that are intended to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients)” must be certified according to the provisions of subpart E of this part and must meet all other applicable requirements of this part.

(b) Any production or handling operation that has been certified by a certifying agent on the date that the certifying agent first receives its accreditation under this part shall be considered certified to the national standards until the operation's anniversary date of certification. Such recognition shall only be available to those operations certified by a certifying agent that receives its accreditation within 18 months from the date of publication of the final rule implementing this part.

§ 205.101 Exemptions and exclusions from certification.

(a) Exemptions.

(1) A production or handling operation that sells agricultural products as “organic” but whose gross agricultural income from organic sales totals \$5,000 or less annually is exempt from certification under subpart E of this part and from submitting an organic system plan for acceptance or approval under § 205.201 but must comply with the applicable organic production and handling requirements of subpart C of this part and the labeling requirements of § 205.309.

(2) A handling operation that is a retail food establishment or portion of a retail food establishment that handles organically produced agricultural products but does not process them is exempt from the requirements in this part.

(3) A handling operation or portion of a handling operation that handles agricultural products that contain less than 50 percent organic ingredients by total weight of the finished product (excluding water and salt) is exempt from the requirements in this part, except:

(i) The provisions for prevention of contact of organic products with prohibited substances set forth in § 205.272 with respect to any organically produced ingredients used in an agricultural product;

(ii) The labeling provisions of § 205.309; and

(iii) The recordkeeping provisions in paragraph (c) of this section.

(4) A handling operation or portion of a handling operation that handles agricultural products that contain at least 50 percent organic ingredients by total weight of the finished product (excluding water and salt) that chooses to not use the word, “organic,” on any panel other than the information panel is exempt from the requirements in this part, except:

(i) The provisions for prevention of contact of organic products with prohibited substances set forth in § 205.272 with respect to any organically produced ingredients used in an agricultural product;

(ii) The labeling provisions of § 205.309; and

(iii) The recordkeeping provisions in paragraph (c) of this section.

(b) Exclusions.

(1) A handling operation or portion of a handling operation is excluded from the requirements of this part, except for the requirements for the prevention of commingling and contact with prohibited substances as set forth in § 205.272 with respect to any

organically produced products if such operation or portion of the operation only sells organic agricultural products labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients)” that:

(i) Are packaged or otherwise enclosed in a container prior to being received or acquired by the operation; and

(ii) Remain in the same package or container and are not otherwise processed while in the control of the handling operation.

(2) A handling operation that is a retail food establishment or portion of a retail food establishment that processes or prepares, on the premises of the retail food establishment, raw and ready-to-eat food from agricultural products that are previously labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients)” is excluded from the requirements in this part, except:

(i) The requirements for the prevention of contact with prohibited substances as set forth in § 205.272; and

(ii) The labeling provisions of § 205.309.

(c) Records to be maintained by exempt operations.

(1) Any handling operation exempt from certification pursuant to paragraph (a)(3) or (a)(4) of this section must maintain records sufficient to:

(i) Prove that ingredients identified as organic were organically produced and handled; and

(ii) Verify quantities produced from such ingredients.

(2) Records must be maintained for no less than 3 years beyond their creation and the operations must allow representatives of the Secretary and the applicable State program's governing State official access to these records for inspection and copying during normal business hours to determine compliance with the applicable regulations set forth in this part.

§ 205.102 Use of the term, “organic.”

Any agricultural product that is sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients)” must be:

(a) Produced in accordance with the requirements specified in § 205.101 or §§ 205.202 through 205.207 or §§ 205.236 through 205.239 and all other applicable requirements of part 205;

(b) Handled in accordance with the requirements specified in § 205.101 or §§ 205.270 through 205.272 and all other applicable requirements of this part 205; and

(c) Produced and handled in compliance with the Federal Meat

Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), and the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*), concerning meat, poultry, and egg products; the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*); the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*); and any other applicable Federal statute and its implementing regulations.

§ 205.103 Recordkeeping by certified operations.

(a) A certified operation must maintain records concerning the production, harvesting, and handling of agricultural products that are or that are intended to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients).”

(b) Such records must:

- (1) Be adapted to the particular business that the certified operation is conducting;
- (2) Fully disclose all activities and transactions of the certified operation in sufficient detail as to be readily understood and audited;
- (3) Be maintained for not less than 5 years beyond their creation; and
- (4) Be sufficient to demonstrate compliance with the Act and the regulations in this part.

(c) The certified operation must make such records available for inspection and copying during normal business hours by authorized representatives of the Secretary, the applicable State program’s governing State official, and the certifying agent.

§ 205.104 Foreign applicants.

The regulations in this part, as applicable, apply equally to domestic and foreign applicants for accreditation, accredited certifying agents, domestic and foreign applicants for certification as organic production or handling operations, and certified organic production and handling operations unless otherwise specified.

§§ 205.105–205.199 [Reserved]

Subpart C—Organic Production and Handling Requirements

§ 205.200 General.

The producer or handler of a production or handling operation wishing to sell, label, or represent agricultural products as “100 percent organic,” “organic,” or “made with organic (specified ingredients)” must comply with the applicable provisions of this subpart. Practices implemented in accordance with this subpart must maintain or improve the natural

resources of the operation, including soil and water quality.

§ 205.201 Organic production and handling system plan.

(a) The producer or handler of a production or handling operation, except as exempt or excluded under § 205.101, wishing to sell, label, or represent agricultural products as “100 percent organic,” “organic,” or “made with organic (specified ingredients)” must develop an organic production or handling system plan that is agreed to by the producer or handler and an accredited certifying agent. An organic system plan must meet the requirements set forth in this section to establish a system of organic production or handling. An organic production or handling system plan must include:

- (1) A description of practices and procedures to be performed and maintained, including the frequency with which they will be performed;
- (2) A list of each substance to be used as a production or handling input, indicating its composition, source, and location(s) where it will be used;
- (3) A description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented;
- (4) A description of the recordkeeping system implemented to comply with the requirements established in § 205.103;
- (5) A description of practices and procedures to prevent commingling of organic and nonorganic products and to prevent contact of organic production and handling operations and products with prohibited substances; and
- (6) Additional information deemed necessary by the certifying agent to evaluate compliance with the regulations.

(b) A producer may substitute a plan prepared to meet the requirements of another Federal, State, or local government regulatory program for the organic system plan: *Provided*, That, the submitted plan meets all the requirements of this subpart.

§ 205.202 Land requirements.

Any field or farm parcel from which harvested crops are intended to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients)” must:

- (a) Have been managed in accordance with the provisions of §§ 205.203 through 205.206;
- (b) Have had no prohibited substances, as listed in § 205.600, applied to it for a period of 3 years immediately preceding harvest of the crop; and

(c) Have distinct, defined boundaries and buffer zones such as runoff diversions to prevent the unintended application of a prohibited substance to the crop or contact with a prohibited substance applied to adjoining land that is not under organic management.

§ 205.203 Soil fertility and crop nutrient management practice standard.

(a) The producer must select and implement tillage and cultivation practices that maintain or improve the physical, chemical, and biological condition of soil and minimize soil erosion.

(b) The producer must budget and supply crop nutrients by properly utilizing manure or other animal and plant materials, mined mineral substances, and substances approved in § 205.601.

(c) The producer must manage animal and plant waste materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances. Animal and plant waste materials include:

- (1) Raw animal manure, which must be composted unless it is:
 - (i) Applied to land used for a crop not intended for human consumption;
 - (ii) Incorporated into the soil not less than 120 days prior to the harvest of a product whose edible portion has direct contact with the soil surface or soil particles; or
 - (iii) Incorporated into the soil not less than 90 days prior to the harvest of a product whose edible portion does not have direct contact with the soil surface or soil particles;
- (2) Other uncomposted plant or animal wastes, such as aged, fully decomposed animal manure;

(3) A composted product produced in a facility in compliance with the Natural Resources Conservation Service’s practice standard for a composting facility (Code 317); and

(4) A composted or uncomposted plant or animal waste material that has been chemically altered by a manufacturing process: *Provided*, That, the material is included on the National List of synthetic substances allowed for use in organic crop production established in § 205.601.

(d) In addition to crop rotations and plant and animal waste materials, a producer may supply soil and crop nutrients by applying:

- (1) A mined substance of low solubility;
- (2) A mined substance of high solubility, when justified by soil or crop tissue analysis;

(3) Ash obtained from the burning of a plant or animal material, except as prohibited in paragraph (e) of this section: *Provided*, That, the material burned has not been treated or combined with a prohibited substance or the ash is not included on the National List of nonsynthetic substances prohibited for use in organic crop production; and

(4) A crop nutrient supplement included on the National List of synthetic substances allowed for use in organic production, when justified by soil or crop tissue analysis.

(e) The producer must not use:

(1) Any fertilizer or commercially blended fertilizer or composted product that contains a synthetic substance not included on the National List of synthetic substances allowed for use in organic production;

(2) Sewage sludge (biosolids) as defined in 40 CFR part 503; and

(3) Burning as a means of disposal for crop residues produced on the operation: *Except*, That, prunings from perennial crops may be burned to suppress the spread of disease.

§ 205.204 Seeds and planting stock practice standard.

(a) The producer must use organically grown seeds, annual seedlings, and planting stock: *Except*, That,

(1) Nonorganically produced untreated seeds and planting stock may be used to produce an organic crop when an equivalent organically produced variety is not commercially available;

(2) Nonorganically produced seeds and planting stock that have been treated with a substance included on the National List of synthetic substances allowed for use in organic crop production may be used to produce an organic crop when an equivalent organically produced or untreated variety is not commercially available;

(3) Nonorganically produced annual seedlings may be used to produce an organic crop when a temporary variance has been granted in accordance with § 205.290(a)(2);

(4) Nonorganically produced planting stock to be used to produce a perennial crop may be sold, labeled, or represented as organically produced only after the planting stock has been maintained under a system of organic management for a period of no less than 1 year; and

(5) Seeds, annual seedlings, and planting stock treated with prohibited substances may be used to produce an organic crop when the application of the materials is a requirement of Federal or State phytosanitary regulations.

(b) The producer of an organic operation must not use seeds or planting stock produced with excluded methods.

§ 205.205 Crop rotation practice standard.

The producer must implement a crop rotation including, but not limited to, sod, cover crops, green manure crops, and catch crops that provide the following functions that are applicable to the operation:

(a) Maintain or improve soil organic matter content;

(b) Provide for pest management in annual and perennial crops;

(c) Manage deficient or excess plant nutrients; and

(d) Provide erosion control.

§ 205.206 Crop pest, weed, and disease management practice standard.

(a) The producer must use management practices to prevent crop pests, weeds, and diseases including, but not limited to:

(1) Crop rotation and soil and crop nutrient management practices, as provided for in §§ 205.203 and 205.205;

(2) Sanitation measures to remove disease vectors, weed seeds, and habitat for pest organisms; and

(3) Cultural practices that enhance crop health, including selection of plant species and varieties with regard to suitability to site-specific conditions and resistance to prevalent pests, weeds, and diseases.

(b) Pest problems may be controlled through mechanical or physical methods including, but not limited to:

(1) Augmentation or introduction of predators or parasites of the pest species;

(2) Development of habitat for natural enemies of pests;

(3) Nonsynthetic, nontoxic controls such as lures, traps, and repellents.

(c) Weed problems may be controlled through:

(1) Mulching with fully biodegradable materials;

(2) Mowing;

(3) Livestock grazing;

(4) Hand weeding and mechanical cultivation;

(5) Flame, heat, or electrical means; or

(6) Plastic or other synthetic mulches: *Provided*, That, they are removed from the field at the end of the growing or harvest season.

(d) Disease problems may be controlled through:

(1) Management practices which suppress the spread of disease organisms; or

(2) Application of nonsynthetic biological, botanical, or mineral inputs.

(e) When the practices provided for in paragraphs (a) through (d) of this section

are insufficient to prevent or control crop pests, weeds, and diseases, a biological or botanical substance or a substance included on the National List of synthetic substances allowed for use in organic production may be applied to prevent, suppress, or control pests, weeds, or diseases: *Provided*, That, the producer implements measures to evaluate and mitigate the effects of repetitive use of the same or similar materials on pest resistance and shifts in pest, weed, or disease types, and the substance is used in compliance with the Federal Insecticide, Fungicide, and Rodenticide Act.

(f) The producer or handler of an organic operation must not use a pest, weed, or disease control substance produced through excluded methods.

§ 205.207 Wild-crop harvesting practice standard.

(a) Any area from which a wild crop that is intended to be sold, labeled, or represented as organic is harvested must have had no prohibited substance, as set forth in § 205.600, applied to it for a period of 3 years immediately preceding the harvest of the wild crop.

(b) A wild-crop must be harvested in a manner that ensures that such harvesting or gathering will not be destructive to the environment and will sustain the growth and production of the wild crop.

§§ 205.208—205.235 [Reserved]

§ 205.236 Origin of livestock.

(a) Livestock or edible livestock products that are to be sold, labeled, or represented as organic must be from livestock under continuous organic management from birth or hatching: *Except*, That,

(1) *Poultry*. Poultry or edible poultry products must be from poultry that has been under continuous organic management beginning no later than the second day of life;

(2) *Dairy Animals*. Milk or milk products must be from animals that have been under continuous organic management beginning no later than 1 year prior to the production of the milk or milk products that are to be sold, labeled, or represented as organic.

(3) *Nonedible products*. Nonedible livestock products must be from animals that have been under continuous organic management not less than 1 year prior to harvest of the nonedible product.

(4) *Breeder stock*. Livestock used as breeder stock may be brought from a nonorganic operation onto an organic operation at any time: *Provided*, That, if such livestock are gestating and the offspring are to be raised as organic

livestock, the breeder stock must be brought onto the facility prior to the last third of pregnancy.

(b) The following are prohibited:

(1) Livestock or edible livestock products that are removed from an organic operation and subsequently managed on a nonorganic operation may be not sold, labeled, or represented as organically produced.

(2) Breeder or dairy stock that has not been under continuous organic management since birth may not be sold, labeled, or represented as organic slaughter stock; and

(3) No organism produced by excluded methods may be used for breeding purposes or for the production of livestock products intended to be sold, labeled, or represented as organic.

(c) The producer of an organic livestock operation must maintain records sufficient to preserve the identity of all organically managed animals and edible and nonedible animal products produced on the operation.

§ 205.237 Livestock feed.

(a) The producer of an organic livestock operation must provide livestock with a total feed ration composed of agricultural products, including pasture and forage, that is organically produced and, if applicable, organically handled: *Except*, That, nonagricultural products and synthetic substances allowed under § 205.603 may be used as feed additives and supplements.

(b) The producer of an organic operation must not:

(1) Use animal drugs, including hormones, to promote growth;

(2) Provide feed supplements or additives in amounts above those needed for adequate nutrition and health maintenance for the species at its specific stage of life;

(3) Feed plastic pellets for roughage;

(4) Feed formulas containing urea or manure;

(5) Feed mammalian or poultry slaughter by-products to mammals or poultry; or

(6) Use feed, feed additives, and feed supplements in violation of the Federal Food, Drug, and Cosmetic Act.

§ 205.238 Livestock health care practice standard.

(a) The producer must establish and maintain preventive livestock health care practices, including:

(1) Selection of species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites;

(2) Provision of feedstuffs sufficient to meet nutritional requirements,

including vitamins, minerals, and other additives or supplements;

(3) Establishment of appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of diseases and parasites;

(4) Provision of conditions which allow for exercise, freedom of movement, and reduction of stress appropriate to the species;

(5) Performance of physical alterations as needed to promote the animal's welfare and in a manner that minimizes pain and stress; and

(6) Administration of vaccines and other veterinary biologics.

(b) When preventive practices and veterinary biologics are inadequate to prevent sickness, a producer may administer synthetic medications:

Provided, That, such medications are allowed under § 205.603. Parasiticides allowed under § 205.603 may be used on

(1) Breeder stock, when used prior to the last third of gestation for progeny that are to be sold, labeled, or represented as organically produced; and

(2) Dairy stock, when used a minimum of 90 days prior to the production of milk or milk products that are to be sold, labeled, or represented as organic.

(c) The producer of an organic livestock operation must not:

(1) Sell, label, or represent as organic any animal or edible product derived from any animal treated with antibiotics, any substance that contains a synthetic substance not allowed under § 205.603, or any substance that contains a nonsynthetic substance prohibited in § 205.604.

(2) Administer any animal drug, other than vaccinations, in the absence of illness;

(3) Administer hormones;

(4) Administer synthetic parasiticides on a routine basis;

(5) Administer synthetic parasiticides to slaughter stock;

(6) Administer animal drugs in violation of the Federal Food, Drug, and Cosmetic Act; or

(7) Withhold medical treatment from a sick animal in an effort to preserve its organic status. All appropriate medications must be used to restore an animal to health when methods acceptable to organic production fail. Livestock treated with a prohibited substance must be clearly identified and shall not be sold, labeled, or represented as organically produced.

§ 205.239 Livestock living conditions.

(a) The producer of an organic livestock operation must establish and

maintain livestock living conditions which accommodate the health and natural behavior of animals, including:

(1) Access to shade, shelter, exercise areas, fresh air, and direct sunlight suitable to the species, its stage of production, the climate, and the environment;

(2) Access to pasture for ruminants;

(3) Appropriate clean, dry bedding. If the bedding is typically consumed by the animal species, it must comply with the feed requirements of § 205.237;

(4) Shelter designed to allow for:

(i) Natural maintenance, comfort behaviors, and opportunity to exercise;

(ii) Temperature level, ventilation, and air circulation suitable to the species; and

(iii) Reduction of potential for livestock injury;

(b) The producer of an organic livestock operation may provide temporary confinement for an animal because of:

(1) Inclement weather;

(2) The animal's stage of production;

(3) Conditions under which the health, safety, or well being of the animal could be jeopardized; or

(4) Risk to soil or water quality.

(c) The producer of an organic livestock operation must manage manure in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, heavy metals, or pathogenic organisms and optimizes recycling of nutrients.

§§ 205.240–205.269 [Reserved]

§ 205.270 Organic handling requirements.

(a) Mechanical or biological methods, including, but not limited to, cooking, baking, heating, drying, mixing, grinding, churning, separating, extracting, slaughtering, cutting, fermenting, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing, and the packaging, canning, jarring, or otherwise enclosing food in a container may be used to process an agricultural product intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients)" for the purpose of retarding spoilage or otherwise preparing the agricultural product for market.

(b) Nonagricultural substances allowed under § 205.605 and nonorganically produced agricultural products allowed under § 205.606 may be used in or on a processed agricultural product intended to be sold, labeled, or represented as "organic" or "made with organic (specified ingredients)."

(c) The handler of an organic handling operation must not use in or on an

agricultural product intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients)":

- (1) Ionizing radiation for any purpose;
- (2) An ingredient produced with excluded methods; or
- (3) A volatile synthetic solvent or any other synthetic processing aid not allowed under § 205.605 as ingredients in or on processed products labeled as organic or made with organic ingredients.

§ 205.271 Facility pest management practice standard.

(a) The producer or handler of an organic facility must use management practices to prevent pests, including, but not limited to:

- (1) Removal of pest habitat, food sources, and breeding areas;
 - (2) Prevention of access to handling facilities; or
 - (3) Management of environmental factors, such as temperature, light, humidity, atmosphere, and air circulation to prevent pest reproduction.
- (b) Pests may be controlled through:
- (1) Augmentation or introduction of predators or parasites for the pest species;
 - (2) Mechanical or physical controls including, but not limited to, traps, light, or sound; or
 - (3) Nontoxic, nonsynthetic controls, such as lures and repellents.

(c) If the practices provided for in paragraphs (a) and (b) of this section are not effective to prevent or control facility pests, a nonsynthetic biological or botanical substance or a synthetic substance may be applied to prevent, suppress, or control pests: *Provided*, That, the substance is applied in the manner consistent with its label as approved by the Federal, State, and local regulatory authorities.

(d) The handler of an organic handling operation who applies a nonsynthetic biological or botanical substance or a synthetic substance for the prevention or control of a pest must include in the organic handling plan a list of all measures taken or intended to be taken to prevent contact between the substance and any ingredient or finished product intended to be sold, labeled, or represented as "organic" or "made with organic (specified ingredients)."

(e) The handler of an organic handling operation who applies a nonsynthetic biological or botanical substance or a synthetic substance for the prevention or control of a pest must include in the organic handling plan an evaluation of the effects of repetitive use of the same or similar materials on pest resistance and shifts in pest types.

§ 205.272 Commingling and contact with prohibited substance prevention practice standard.

(a) The handler of an organic handling operation must implement measures necessary to prevent the commingling of organic and nonorganic products and protect organic products from contact with prohibited substances.

(b) The following methods and substances are prohibited for use in the handling of any agricultural product intended to be sold, labeled, or represented as "100 per cent organic," "organic," or "made with organic (specified ingredients)":

- (1) Packaging materials and storage containers or bins that contain a synthetic fungicide, preservative, or fumigant;
- (2) The use or reuse of any bag or container that had previously been in contact with any substance in such a manner as to compromise the organic integrity of any products unless, after use for conventional products, the reusable bin or container has been thoroughly cleaned and poses no risk of prohibited materials contacting the organic product.

§§ 205.273–205.289 [Reserved]

§ 205.290 Temporary variances.

(a) Temporary variances from the requirements in §§ 205.203 through 205.207, 205.236 through 205.239, and 205.270 through 205.272 may be established by the Administrator for the following reasons:

- (1) Natural disasters declared by the Secretary;
- (2) Damage caused by wind, flood, excessive moisture, tornado, earthquake, fire, or other business interruption; and
- (3) Practices used for the purpose of conducting research or trials of techniques, varieties, or ingredients used in organic production or handling.

(b) A certifying agent may recommend in writing to the Administrator a temporary variance from a standard set forth in subpart C of this part for organic production or handling operations:

Provided, That, such variance may only be recommended for the reasons listed in paragraph (a) of this section.

(c) The Administrator will provide written notification to certifying agents upon establishment of a temporary variance applicable to the certifying agent's certified production or handling operations. When establishing a temporary variance, the Administrator shall specify the period of time it shall remain in effect, subject to extension as the Administrator deems necessary.

(d) A certifying agent, upon notification from the Administrator of

the establishment of a temporary variance, must notify each production or handling operation it certifies within the affected geographical area or the individual organic production or handling operation(s) to which the temporary variance applies.

(e) Temporary variances may not be requested for any practice, material, or procedure otherwise prohibited in these regulations.

Subpart D—Labels, Labeling, and Market Information

§ 205.300 Use of the term, "organic."

(a) The term, "organic," may only be used on labels and in labeling of raw or processed agricultural products, including ingredients, that have been produced and handled in accordance with the regulations in this part.

(b) Products for export, produced and certified to foreign national organic standards or foreign contract buyer requirements, may be labeled in accordance with the organic labeling requirements of the receiving country or contract buyer: *Provided*, That, the shipping containers and shipping documents meet the labeling requirements specified in § 205.306(c).

(c) Products produced in a foreign country and exported for sale in the United States must be certified pursuant to subpart E of this part and labeled pursuant to this subpart D.

§ 205.301 Product composition.

(a) *Products sold, labeled, or represented as "100 percent organic."* A raw or processed agricultural product sold, labeled, or represented as "100 percent organic" must contain (by weight or fluid volume, excluding water and salt) not less than 100 percent organically produced raw or processed agricultural product. No such product or product ingredient may contain or be created using excluded methods or be produced using sewage sludge or ionizing radiation. If labeled as an organic food product, such product must be labeled pursuant to § 205.303.

(b) *Products sold, labeled, or represented as "organic."* A raw or processed agricultural product sold, labeled, or represented as "organic" must contain (by weight or fluid volume, excluding water and salt) not less than 95 percent organically produced raw or processed agricultural product. Any remaining product ingredients must consist of nonagricultural substances or nonorganically produced agricultural products approved in the National List of Allowed and Prohibited Substances in subpart G of this part and must not

contain or be created using excluded methods or be produced using sewage sludge or ionizing radiation. If labeled as an organic food product, such products must be labeled pursuant to § 205.303.

(c) *Products sold, labeled, or represented as "made with organic (specified ingredients)."* Multiingredient agricultural product sold, labeled, or represented as "made with organic (specified ingredients)" must contain (by weight or fluid volume, excluding water and salt) at least 50 percent organically produced agricultural products which are produced and handled pursuant to requirements in subpart C of this part. The nonorganic ingredients must not contain or be created using excluded methods or be produced using sewage sludge or ionizing radiation. If labeled as an organic food product, such products must be labeled pursuant to § 205.304.

(d) *Products with less than 50 percent organic ingredients.* The organic ingredients in multiingredient agricultural product containing less than 50 percent organic ingredients (by weight or fluid volume, excluding water and salt) must be produced and handled pursuant to requirements in subpart C of this part. The nonorganic ingredients may be produced and handled without regard to the requirements of this part. Multiingredient agricultural product containing less than 50 percent organically produced ingredients may represent the organic nature of the product only as provided in § 205.305.

(e) All ingredients identified as "organic" in the ingredient statement of any product must not:

(1) Be produced using excluded methods or products of excluded methods as ingredients or processing aids;

(2) Be produced using sewage sludge;

(3) Be processed using ionizing radiation;

(4) Be processed using processing aids not approved on the National List of Allowed and Prohibited Substances in subpart G of this part: *Except*, That, products labeled as "100 percent organic," if processed, must be processed using no processing aids;

(5) Contain sulfites, nitrates, or nitrites added during the production or handling process;

(6) Be produced using nonorganic ingredients when organic ingredients are not available; or

(7) Include organic and nonorganic forms of the same ingredient.

§ 205.302 Calculating the percentage of organically produced ingredients.

(a) The percentage of all organically produced ingredients in an agricultural product sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients)," or that include organic ingredients must be calculated by:

(1) Dividing the total net weight (excluding water and salt) of combined organic ingredients by the total weight (excluding water and salt) of the finished product.

(2) Dividing the fluid volume of all organic ingredients (excluding water and salt) by the fluid volume of the finished product (excluding water and salt) if the product and ingredients are liquid. If the liquid product is identified on the principal display panel or information panel as being reconstituted from concentrates, the calculation should be made on the basis of single-strength concentrations of the ingredients and finished product.

(3) For products containing organic ingredients in both solid and liquid form, dividing the combined weight of the solid ingredients and the weight of the liquid ingredients (excluding water and salt) by the total weight (excluding water and salt) of the finished product.

(b) The percentage of all organically produced ingredients in an agricultural product must be rounded down to the nearest whole number and indicated on the information panel above the ingredient statement with the words, "contains X percent organic ingredients."

(c) The percentage must be calculated by the handler who affixes the label on the consumer package and verified by the certifying agent of the handler.

§ 205.303 Packaged products labeled "100 percent organic" or "organic."

(a) Agricultural products in packages described in § 205.301(a) and (b) may display, on the principal display panel, information panel, and any other panel of the package and on any labeling or market information concerning the product, the following terms:

(1) The term, "100 percent organic" or "organic," as applicable, to modify the name of the product;

(2) The USDA Seal;

(3) The seal, logo, or other identifying mark of the certifying agent which certified the production or handling operation producing the finished product and any other certifying agent which certified production or handling operations producing raw organic product or organic ingredients used in the finished product: *Provided*, That, the handler producing the finished

product maintain records, pursuant to this part, verifying organic certification of the operations producing such ingredients, and: *Provided further*, That, such seals or marks are not, individually, displayed more prominently than the USDA Seal.

(b) Agricultural products in packages described in § 205.301(a) and (b) must:

(1) On the information panel of multiingredient products and consistent with the labeling requirements of the Food and Drug Administration, declare the total percentage of organic ingredients in the product.

(2) In the ingredient statement, modify each organic ingredient of multiingredient products with the word, "organic": *Except*, That, ingredients in multiingredient products labeled "100 percent organic" are not required to be modified with the term "organic." Any water or salt included as an ingredient will not be identified as organic.

(3) On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, "Certified organic by * * *," or similar phrase, identify the name of the certifying agent that certified the handler of the finished product: *Except*, That, the business address or telephone number of the certifying agent may be included in such label.

§ 205.304 Packaged products labeled "made with organic (specified ingredients)."

(a) Agricultural products in packages described in § 205.301(c) may display on the principal display panel, information panel, and any other panel and on any labeling or market information concerning the product:

(1) The statement, "made with organic (specified ingredients)": *Provided*, That, display of the statement is consistent with labeling requirements of the Food and Drug Administration and:

(i) Does not list more than three organic ingredients;

(ii) Does not exceed one-half the size of the largest type size on the panel; and

(iii) Appears in its entirety in the same type size, style, and color without highlighting; and

(2) The seal, logo, or other identifying mark of the certifying agent that certified the handler of the finished product.

(b) Agricultural products in packages described in § 205.301(c) must:

(1) On the information panel and consistent with the labeling requirements of the Food and Drug Administration, declare the total percentage of organic ingredients in the product.

(2) In the ingredient statement, modify each organic ingredient with the word, "organic." Any water or salt included as an ingredient will not be identified as organic.

(3) On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, "Certified organic by * * *," or similar phrase, identify the name of the certifying agent that certified the handler of the finished product: *Except*, That, the business address or telephone number of the certifying agent may be included in such label.

(c) Agricultural products in packages described in § 205.301(c) must not display the USDA Seal.

§ 205.305 Multiingredient packaged products with less than 50 percent organic ingredients.

(a) Agricultural products with less than 50 percent organic ingredients must:

(1) On the information panel and consistent with the labeling requirements of the Food and Drug Administration, declare the total percentage of organic ingredients in the product.

(2) In the ingredient statement, modify each organic ingredient with the word, "organic."

(b) Agricultural products with less than 50 percent organic ingredients must not display:

- (1) The USDA Seal and
- (2) Any certifying agent's seal, logo, or other identifying mark.

§ 205.306 Labeling of nonretail containers used for only shipping or storage of raw or processed agricultural products labeled as "100 percent organic," "organic," or "made with organic (specified ingredients)."

(a) Nonretail containers used only to ship or store raw or processed agricultural product labeled as containing organic ingredients may display the following terms or marks:

(1) The name and contact information of the certifying agent which certified the handler which assembled the final product;

(2) Identification of the product as "organic product";

(3) Special handling instructions needed to maintain the organic integrity of the product;

(4) The USDA Seal;

(5) The seal, logo, or other identifying mark of the certifying agent that certified the organic production or handling operation that produced or handled the finished product.

(b) If not required under other Federal labeling regulations, nonretail containers used to ship or store raw or

processed agricultural product labeled as containing organic ingredients must display the production lot number of the product, if applicable.

(c) Shipping containers of domestically produced product labeled as organic intended for export to international markets may be labeled consistent with any shipping container labeling requirements of the foreign country of destination or the container labeling specifications of a foreign contract buyer: *Provided*, That, the shipping containers and shipping documents accompanying such organic product be clearly marked "For export only" and: *Provided further*, That, proof of such container marking and export must be maintained by the handler, consistent with recordkeeping requirements for exempt and excluded operations under § 205.101.

§ 205.307 Agricultural products in other than packaged form at the point of retail sale that are sold, labeled, or represented as "100 percent organic" or "organic."

(a) Agricultural products labeled or represented as "100 percent organic" or "organic" in retail display, labeling, and display containers may use the term, "100 percent organic" or "organic," as applicable, to modify the name of the product: *Provided*, That, such products are assembled in a manufacturing facility certified in accordance with the requirements of this part; and, *Provided further*, Than, the word, "organic," is used to modify the organic ingredients listed in the ingredient statement of the products.

(b) The retail display, labeling, and display containers may use:

- (1) The USDA Seal;
- (2) The seal, logo, or other identifying mark of the certifying agent that certified the production or handling operation producing the finished product and any other certifying agent which certified operations producing raw organic product or organic ingredients used in the finished product: *Provided*, That, such seals or marks are not, individually, displayed more prominently than the USDA Seal.

§ 205.308 Agricultural products in other than packaged form at the point of retail sale that are sold, labeled, or represented as "made with organic (specified ingredients)."

(a) Retail displays, display containers, and market information of agricultural products containing between 50 and 95 percent organic ingredients may use the phrase, "made with organic (specified ingredients)" *Provided*, That, such products have been assembled at a manufacturing facility certified in

accordance with the requirements of this part, and:

(1) Such statement does not list more than three organic ingredients, and

(2) In any such display of the product's ingredient statement, the organic ingredients must be modified as "organic."

(b) Such agricultural products labeled as "made with organic (specified ingredients)" in retail displays, display containers, and market information may display the certifying agent's seal, logo, or other identifying mark.

§ 205.309 Agricultural products produced on an exempt or excluded operation.

(a) An agricultural product organically produced or handled on an exempt or excluded operation must not:

(1) Display the USDA Seal or any certifying agent's seal or other identifying mark which represents that the production or handling operation as a certified organic operation, or

(2) Be represented as a certified organic product to any buyer.

(b) An agricultural product organically produced or handled on an exempt or excluded operation may be identified as an organic product or organic ingredient in a multiingredient product produced by the exempt or excluded operation. Such product or ingredient must not be identified as "organic" in a product processed by others.

(c) Such product is subject to labeling requirements specified in paragraph (a) of § 205.300, and paragraphs (e)(1) through (e)(7) of § 205.301.

§ 205.310 USDA Seal.

(a) The USDA Seal described in paragraphs (b) and (c) of this section may be used only for agricultural products (raw or processed) described in § 205.301(a) and (b).

(b) The USDA Seal must replicate the form and design of the example in figure 1 and must be printed legibly and conspicuously:

(1) On a white, light colored, or transparent background with contrasting dark color words and shield outline or on a dark colored background with contrasting white or light colored words and shield outline; or

(2) On a white background with dark blue colored words and red shield outline.



Figure 1

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Subpart E—Certification**§ 205.400 General requirements for certification.**

A person seeking to receive or maintain organic certification under the regulations in this part must:

- (a) Comply with the Act and applicable organic production and handling regulations of this part;
- (b) Establish, implement, and update annually an organic production or handling system plan that is submitted to an accredited certifying agent as provided for in § 205.200;
- (c) Permit on-site inspections with complete access to the production or handling operation, including noncertified areas and structures, by the certifying agent as provided for in § 205.403;
- (d) Maintain all records applicable to the organic operation for not less than 5 years beyond their creation and allow authorized representatives of the Secretary, the applicable State program's governing State official, and the certifying agent access to such records during normal business hours for review and copying to determine compliance with the Act and the regulations in this part, as provided for in § 205.104;
- (e) Submit the applicable fees charged by the certifying agent; and
- (f) Immediately notify the certifying agent concerning any:
 - (1) Application, including drift, of a prohibited substance to any field, production unit, site, facility, livestock, or product that is part of an operation; and
 - (2) Change in a certified operation or any portion of a certified operation that may affect its compliance with the Act and the regulations in this part.

§ 205.401 Application for Certification.

A person seeking certification of a production or handling operation under this subpart must submit a request for certification to a certifying agent. The

request must include the following information:

- (a) An organic production or handling system plan, as required in § 205.200;
- (b) The name of the person completing the application; the applicant's business name, address, and telephone number; and, when the applicant is a corporation, the name, address, and telephone number of the person authorized to act on the applicant's behalf.
- (c) The name(s) of any organic certifying agent(s) to which application has previously been made, the year(s) of application, and the outcome of the application(s) submission, including a copy of any notification of noncompliance or denial of certification issued to the applicant for certification and a description of the actions taken by the applicant to correct the deficiencies noted in the notification of noncompliance, including evidence of such correction and;
- (d) Other information necessary to determine compliance with the Act and the regulations in this part.

§ 205.402 Review of application.

- (a) Upon acceptance of an application for certification a certifying agent must:
 - (1) Review the application to ensure completeness pursuant to § 205.401;
 - (2) Determine by a review of the application materials whether the applicant appears to comply or may be able to comply with the applicable requirements of subpart C of this part;
 - (3) Verify that an applicant who previously applied to another certifying agent and received a notification of noncompliance, pursuant to § 205.405(a), has submitted documentation to support the correction of any deficiencies identified in such notification, as required in § 205.405(b); and
 - (4) Schedule an on-site inspection of the operation to determine whether the applicant qualifies for certification if the review of application materials reveals that the production or handling operation may be in compliance with the applicable requirements of subpart C of this part.

(b) The certifying agent shall communicate to the applicant its findings on the review of application materials specified in § 205.402(a).

(c) The applicant may withdraw its application at any time. An applicant who withdraws its application shall be liable for the costs of services provided up to the time of withdrawal of its application. An applicant that voluntarily withdrew its application prior to the issuance of a notice of noncompliance will not be issued a

notice of noncompliance. Similarly, an applicant that voluntarily withdrew its application prior to the issuance of a notice of certification denial will not be issued a notice of certification denial.

§ 205.403 On-site inspections.**(a) On-site inspections.**

(1) A certifying agent must conduct an initial on-site inspection of each production unit, facility, and site that is included in an operation for which certification is requested and an on-site inspection of each certified operation annually thereafter, for the purpose of determining whether to approve the request for certification or whether the certification of the operation should continue.

(2)(i) A certifying agent may conduct additional on-site inspections of applicants for certification and certified operations to determine compliance with the Act and the regulations in this part.

(ii) The Administrator or State program's governing State official may require that additional inspections be performed by the certifying agent for the purpose of determining compliance with the Act and the regulations in this part.

(iii) Additional inspections may be announced or unannounced at the discretion of the certifying agent or as required by the Administrator or State program's governing State official.

(b) *Scheduling.* The initial on-site inspection must be conducted within a reasonable time following a determination that the applicant appears to comply or may be able to comply with the requirements of subpart C of this part. On-site inspections must be conducted when the applicant or an authorized representative of the applicant who is knowledgeable about the operation is present and at a time when land, facilities, and activities that demonstrate the operation's compliance with or capability to comply with the applicable provisions of subpart C of this part can be observed, except that this requirement does not apply to unannounced on-site inspections.

(c) *Verification of information.* The on-site inspection of an operation must verify:

(1) The operation's compliance or capability to comply with the Act and the regulations in this part;

(2) That the information, including the organic production or handling system plan, provided in accordance with §§ 205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for

certification or by the certified operation;

(3) That prohibited substances have not been and are not being applied to the operation through means which, at the discretion of the certifying agent, may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples.

(d) *Exit interview.* The inspector must conduct an exit interview with an authorized representative of the inspected operation to confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection. The inspector must also address the need for any additional information as well as any issues of concern.

§ 205.404 Approval of certification.

(a) Within a reasonable time after completion of the initial on-site inspection, a certifying agent must review the on-site inspection report, the results of any analyses for substances conducted, and any additional information requested from or supplied by the applicant. If the certifying agent determines that the organic system plan and all procedures and activities of the applicant's operation are in compliance with the requirements of this part and that the applicant is able to conduct operations in accordance with the plan, the agent shall approve certification. The approval may include restrictions as a condition of continued certification.

(b) The certifying agent must issue a certificate of organic operation which specifies the:

(1) Name and address of the certified operation;

(2) Effective date of certification;

(3) Categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation; and

(4) Name, address, and telephone number of the certifying agent.

(c) Once certified, a production or handling operation's organic certification continues in effect until surrendered by the organic operation or suspended or revoked by the certifying agent, the State program's governing State official, or the Administrator.

§ 205.405 Denial of certification.

(a) When the certifying agent has reason to believe, based on a review of the information specified in § 205.402 or § 205.404, that an applicant for certification is not able to comply or is not in compliance with the requirements of this part, the certifying agent must provide a written notification of noncompliance to the

applicant pursuant to § 205.662(a). When correction of a noncompliance is not possible, a notification of noncompliance and a notification of denial of certification may be combined in one notification.

(b) Upon receipt of such notification of noncompliance, the applicant may:

(1) Correct deficiencies and submit a description of the corrective actions taken with supporting documentation to the certifying agent;

(2) Correct deficiencies and submit a new application to another certifying agent: *Provided*, That, the applicant must include a complete application, the notification of noncompliance received from the first certifying agent, and a description of the corrective actions taken with supporting documentation; or

(3) Submit written information to rebut the noncompliance described in the notification of noncompliance.

(c) After issuance of a notification of noncompliance, the certifying agent must:

(1) Evaluate the applicant's corrective actions taken and supporting documentation submitted or the written rebuttal, conduct an on-site inspection if necessary, and;

(i) When the corrective action or rebuttal is sufficient for the applicant to qualify for certification, issue the applicant an approval of certification pursuant to § 205.404; or

(ii) When the corrective action or rebuttal is not sufficient for the applicant to qualify for certification, issue the applicant a written notice of denial of certification.

(2) Issue a written notice of denial of certification to an applicant who fails to respond to the notification of noncompliance.

(3) Provide notice of approval or denial to the Administrator, pursuant to § 205.501(a)(14).

(d) A notice of denial of certification must state the reason(s) for denial and the applicant's right to:

(1) Reapply for certification pursuant to §§ 205.401 and 205.405(e);

(2) Request mediation pursuant to § 205.663 or, if applicable, pursuant to a State program; or

(3) File an appeal pursuant to § 205.681 or, if applicable, pursuant to a State program of the denial of certification.

(e) An applicant for certification who has received a written notification of noncompliance or a written notice of denial of certification may apply for certification again at any time with any certifying agent, in accordance with §§ 205.401 and 205.405(e). When such applicant submits a new application to

a certifying agent other than the agent who issued the notification of noncompliance or notice of denial of certification, the applicant for certification must include a copy of the notification of noncompliance or notice of denial of certification and a description of the actions taken, with supporting documentation, to correct the deficiencies noted in the notification of noncompliance.

(f) A certifying agent who receives a new application for certification, which includes a notification of noncompliance or a notice of denial of certification, must treat the application as a new application and begin a new application process pursuant to § 205.402.

(g) Notwithstanding paragraph (a) of this section, if a certifying agent has reason to believe that an applicant for certification has willfully made a false statement or otherwise purposefully misrepresented the applicant's operation or its compliance with the certification requirements pursuant to this part, the certifying agent may deny certification pursuant to paragraph (c)(1)(ii) of this section without first issuing a notification of noncompliance.

§ 205.406 Continuation of certification.

(a) To continue certification, a certified operation must annually submit the following information, as applicable, to the certifying agent:

(1) An updated organic production or handling system plan which includes:

(i) A summary statement, supported by documentation, detailing any deviations from, changes to, modifications to, or other amendments made to the previous year's organic system plan during the previous year; and

(ii) Any additions or deletions to the previous year's organic system plan, intended to be undertaken in the coming year, detailed pursuant to § 205.200;

(2) Any additions to or deletions from the information required pursuant to § 205.401(b); and (3) Other information as deemed necessary by the certifying agent to determine compliance with the Act and the regulations in this part.

(b) Following the receipt of the information specified in paragraph (a) of this section, the certifying agent shall arrange and conduct an on-site inspection of the certified operation, pursuant to § 205.403.

(c) If the certifying agent has reason to believe, based on the on-site inspection and a review of the information specified in § 205.404, that a certified operation is not complying with the requirements of the Act and the

regulations in this part, the certifying agent shall provide a written notification of noncompliance to the operation in accordance with § 205.662.

(d) If the certifying agent determines that the certified operation is complying with the Act and the regulations in this part and that any of the information specified on the certificate of organic operation has changed, the certifying agent must issue an updated certificate of organic operation pursuant to § 205.404(b).

§§ 205.407–205.499 [Reserved]

Subpart F—Accreditation of Certifying Agents

§ 205.500 Areas and duration of accreditation.

(a) The Administrator shall accredit a qualified domestic or foreign applicant in the areas of crops, livestock, wild crops, or handling or any combination thereof to certify a domestic or foreign production or handling operation as a certified operation.

(b) Accreditation shall be for a period of 5 years from the date of approval of accreditation pursuant to § 205.506.

(c) In lieu of accreditation under paragraph (a) of this section, USDA will accept a foreign certifying agent's accreditation to certify organic production or handling operations if:

(1) USDA determines, upon the request of a foreign government, that the standards under which the foreign government authority accredited the foreign certifying agent meet the requirements of this part; or

(2) The foreign government authority that accredited the foreign certifying agent acted under an equivalency agreement negotiated between the United States and the foreign government.

§ 205.501 General requirements for accreditation.

(a) A private or State entity accredited as a certifying agent under this subpart must:

(1) Have sufficient expertise in organic production or handling techniques to fully comply with and implement the terms and conditions of the organic certification program established under the Act and the regulations in this part;

(2) Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart;

(3) Carry out the provisions of the Act and the regulations in this part, including the provisions of §§ 205.402 through 205.406 and § 205.670;

(4) Use a sufficient number of adequately trained personnel, including

inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part;

(5) Ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned.

(6) Conduct an annual performance appraisal for each inspector used by the certifying agent and implement measures to correct any deficiencies in compliance with the Act and the regulations in this part that are identified in the appraisal;

(7) Have an annual program evaluation of its certification activities conducted by the certifying agent's staff, an outside auditor, or a consultant who has expertise to conduct such evaluations and implement measures to correct any deficiencies in compliance with the Act and the regulations in this part that are identified in the evaluation;

(8) Provide sufficient information to persons seeking certification to enable them to comply with the applicable requirements of the Act and the regulations in this part;

(9) Maintain all records pursuant to § 205.510(b) and make all such records available for inspection and copying during normal business hours by authorized representatives of the Secretary and the applicable State program's governing State official;

(10) Maintain strict confidentiality with respect to its clients under the applicable organic certification program and not disclose to third parties (with the exception of the Secretary or the applicable State program's governing State official or their authorized representatives) any business-related information concerning any client obtained while implementing the regulations in this part, except as provided for in § 205.504(b)(5);

(11) Prevent conflicts of interest by:

(i) Not certifying a production or handling operation if the certifying agent or a responsibly connected party of such certifying agent has or has held a commercial interest in the production or handling operation, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification;

(ii) Excluding any person, including contractors, with conflicts of interest from work, discussions, and decisions in all stages of the certification process and the monitoring of certified

production or handling operations for all entities in which such person has or has held a commercial interest, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification;

(iii) Not permitting any employee, inspector, contractor, or other personnel to accept payment, gifts, or favors of any kind, other than prescribed fees, from any business inspected, except that a certifying agent that is a not-for-profit organization with an Internal Revenue Code tax exemption, or in the case of a foreign certifying agent a comparable recognition of not-for-profit status from its government, may accept voluntary labor from certified operations;

(iv) Not providing advice concerning organic practices or techniques to any certification applicant or certified operation for a fee, other than as part of the fees under the applicable certification program established under the Act; and

(v) Requiring all persons identified in § 205.504(a)(2) to complete an annual conflict of interest disclosure report.

(12) Accept the certification decisions made by another USDA-accredited certifying agent as equivalent to its own;

(13) Refrain from making false or misleading claims about its accreditation status, the USDA accreditation program for certifying agents, or the nature or qualities of products labeled as organically produced;

(14) Submit to the Administrator:

(i) A copy of any notice of denial of certification issued pursuant to § 205.405, notification of noncompliance, notification of noncompliance correction, notification of proposed suspension or revocation, and notification of suspension or revocation sent pursuant to § 205.662, simultaneously with its issuance and

(ii) On a quarterly calendar basis, the name, address, and telephone number of each operation granted certification;

(15) Charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator;

(16) Pay and submit fees to AMS in accordance with § 205.640; and

(17) Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.

(b) A private or State entity accredited as a certifying agent under this subpart may establish a seal, logo, or other identifying mark to be used by production and handling operations certified by the certifying agent to indicate affiliation with the certifying

agent: *Provided*, That, the certifying agent:

(1) Does not require use of its seal, logo, or other identifying mark on any product sold, labeled, or represented as organically produced as a condition of certification and

(2) Does not require compliance with any production or handling practices other than those provided for in the Act and the regulations in this part as a condition of use of its identifying mark: *Provided*, That, this provision does not apply to States with more restrictive requirements approved by the Secretary or private entity certifying agents certifying production and handling operations within States with more restrictive requirements approved by the Secretary.

(c) A private entity accredited as a certifying agent must:

(1) Hold the Secretary harmless for any failure on the part of the certifying agent to carry out the provisions of the Act and the regulations in this part;

(2) Furnish reasonable security, in an amount and according to such terms as the Administrator may by regulation prescribe, for the purpose of protecting the rights of production and handling operations certified by such certifying agent under the Act and the regulations in this part; and

(3) Transfer to the Administrator and make available to any applicable State program's governing State official all records or copies of records concerning the person's certification activities in the event that the certifying agent dissolves or loses its accreditation.

(d) No private or State entity accredited as a certifying agent under this subpart shall exclude from participation in or deny the benefits of the National Organic Program to any person due to discrimination because of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status.

§ 205.502 Applying for accreditation.

(a) A private or State entity seeking accreditation as a certifying agent under this subpart must submit an application for accreditation which contains the applicable information and documents set forth in §§ 205.503 through 205.505 and the fees required in § 205.640 to: Program Manager, USDA-AMS-TMP-NOP, Room 2945-South Building, PO Box 96456, Washington, DC 20090-6456.

(b) Following the receipt of the information and documents, the Administrator will determine, pursuant to § 205.506, whether the applicant for

accreditation should be accredited as a certifying agent.

§ 205.503 Applicant information.

A private or State entity seeking accreditation as a certifying agent must submit the following information:

(a) The business name, primary office location, mailing address, name of the person(s) responsible for the certifying agent's day-to-day operations, contact numbers (telephone, facsimile, and Internet address) of the applicant, and, for an applicant who is a private person, the entity's taxpayer identification number;

(b) The name, office location, mailing address, and contact numbers (telephone, facsimile, and Internet address) for each of its organizational units, such as chapters or subsidiary offices, and the name of a contact person for each unit;

(c) Each area of operation (crops, wild crops, livestock, or handling) for which accreditation is requested and the estimated number of each type of operation anticipated to be certified annually by the applicant along with a copy of the applicant's schedule of fees for all services to be provided under these regulations by the applicant;

(d) The type of entity the applicant is (e.g., government agricultural office, for-profit business, not-for-profit membership association) and for:

(1) A State entity, a copy of the official's authority to conduct certification activities under the Act and the regulations in this part,

(2) A private entity, documentation showing the entity's status and organizational purpose, such as articles of incorporation and by-laws or ownership or membership provisions, and its date of establishment; and

(e) A list of each State or foreign country in which the applicant currently certifies production and handling operations and a list of each State or foreign country in which the applicant intends to certify production or handling operations.

§ 205.504 Evidence of expertise and ability.

A private or State entity seeking accreditation as a certifying agent must submit the following documents and information to demonstrate its expertise in organic production or handling techniques; its ability to fully comply with and implement the organic certification program established in §§ 205.100 and 205.101, §§ 205.201 through 205.203, §§ 205.300 through 205.303, §§ 205.400 through 205.406, and §§ 205.661 and 205.662; and its ability to comply with the requirements for accreditation set forth in § 205.501:

(a) *Personnel.*

(1) A copy of the applicant's policies and procedures for training, evaluating, and supervising personnel;

(2) The name and position description of all personnel to be used in the certification operation, including administrative staff, certification inspectors, members of any certification review and evaluation committees, contractors, and all parties responsibly connected to the certifying agent;

(3) A description of the qualifications, including experience, training, and education in agriculture, organic production, and organic handling, for:

(i) Each inspector to be used by the applicant and

(ii) Each person to be designated by the applicant to review or evaluate applications for certification; and

(4) A description of any training that the applicant has provided or intends to provide to personnel to ensure that they comply with and implement the requirements of the Act and the regulations in this part.

(b) *Administrative policies and procedures.*

(1) A copy of the procedures to be used to evaluate certification applicants, make certification decisions, and issue certification certificates;

(2) A copy of the procedures to be used for reviewing and investigating certified operation compliance with the Act and the regulations in this part and the reporting of violations of the Act and the regulations in this part to the Administrator;

(3) A copy of the procedures to be used for complying with the recordkeeping requirements set forth in § 205.501(a)(9);

(4) A copy of the procedures to be used for maintaining the confidentiality of any business-related information as set forth in § 205.501(a)(10);

(5) A copy of the procedures to be used for making the following information available to any member of the public upon request:

(i) Certification certificates issued during the current and 3 preceding calendar years;

(ii) A list of producers and handlers whose operations it has certified, including for each the name of the operation, type(s) of operation, and the effective date of the certification, during the current and 3 preceding calendar years;

(iii) The results of laboratory analyses for residues of pesticides and other prohibited substances conducted during the current and 3 preceding calendar years; and

(iv) Other business information as permitted in writing by the producer or handler; and

(6) A copy of the procedures to be used for sampling and residue testing pursuant to § 205.670.

(c) Conflicts of interest.

(1) A copy of procedures intended to be implemented to prevent the occurrence of conflicts of interest, as described in § 205.501(a)(11).

(2) For each person identified in § 205.504(a)(2), a conflict of interest disclosure report, identifying any food- or agriculture-related business interests, including business interests of immediate family members, that cause a conflict of interest.

(d) Current certification activities. An applicant who currently certifies production or handling operations must submit:

(1) A list of all production and handling operations currently certified by the applicant;

(2) Copies of at least 3, the Administrator may require additional, different inspection reports and certification evaluation documents for production or handling operations certified by the applicant during the previous year for each area of operation for which accreditation is requested; and

(3) The results of any accreditation process of the applicant's operation by an accrediting body during the previous year for the purpose of evaluating its certification activities.

(e) Other information. Any other information the applicant believes may assist in the Administrator's evaluation of the applicant's expertise and ability.

§ 205.505 Statement of agreement.

(a) A private or State entity seeking accreditation under this subpart must sign and return a statement of agreement prepared by the Administrator which affirms that, if granted accreditation as a certifying agent under this subpart, the applicant will carry out the provisions of the Act and the regulations in this part, including:

(1) Accept the certification decisions made by another USDA accredited certifying agent as equivalent to its own;

(2) Refrain from making false or misleading claims about its accreditation status, the USDA accreditation program for certifying agents, or the nature or qualities of products labeled as organically produced;

(3) Conduct an annual performance appraisal for each inspector to be used by the certifying agent and implement measures to correct any possible deficiencies identified in compliance with the Act and the regulations in this part;

(4) Have an annual internal program evaluation conducted of its certification

activities by certifying agent staff, an outside auditor, or a consultant who has the expertise to conduct such evaluations and implement measures to correct any deficiencies identified in compliance with the Act and the regulations in this part;

(5) Pay and submit fees to AMS in accordance with § 205.640; and

(6) Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.

(b) A private entity seeking accreditation as a certifying agent under this subpart must additionally agree to:

(1) Hold the Secretary harmless for any failure on the part of the certifying agent to carry out the provisions of the Act and the regulations in this part;

(2) Furnish reasonable security, in an amount and according to such terms as the Administrator may by regulation prescribe, for the purpose of protecting the rights of production and handling operations certified by such certifying agent under the Act and the regulations in this part; and

(3) Transfer to the Administrator and make available to the applicable State program's governing State official all records or copies of records concerning the certifying agent's certification activities in the event that the certifying agent dissolves or loses its accreditation.

§ 205.506 Approval of accreditation.

(a) Accreditation will be approved when:

(1) The accreditation applicant has submitted the information required by §§ 205.503 through 205.505;

(2) The accreditation applicant pays the required fee in accordance with § 205.640(c); and

(3) The Administrator determines that the applicant for accreditation meets the requirements for accreditation as stated in § 205.501, as determined by a review of the information submitted in accordance with §§ 205.503 through 205.505 and, if necessary, a review of the information obtained from a site evaluation as provided for in § 205.508.

(b) On making a determination to approve an application for accreditation, the Administrator will notify the applicant of approval of accreditation in writing, stating:

(1) The area(s) for which accreditation is given;

(2) The effective date of the accreditation; and

(3) For a certifying agent who is a private entity, the amount and type of security that must be established to protect the rights of production and handling operations certified by such certifying agent.

(c) The accreditation of a certifying agent shall continue in effect until such time as the certifying agent fails to renew accreditation as provided in § 205.510(b), the certifying agent voluntarily ceases its certification activities, or accreditation is suspended or revoked pursuant to § 205.665.

§ 205.507 Denial of accreditation.

(a) If the Administrator has reason to believe, based on a review of the information specified in §§ 205.503 through 205.505 or after a site evaluation as specified in § 205.508, that an applicant for accreditation is not able to comply or is not in compliance with the requirements of the Act and the regulations in this part, the Administrator shall provide a written notification of noncompliance to the applicant in accordance with § 205.665(a).

(b) The applicant may:

(1) File, with the Administrator, an appeal of the deficiencies identified in the notification of noncompliance; or

(2) Submit to the Administrator a description of the actions taken to correct the deficiencies identified in the notification of noncompliance and evidence demonstrating such corrections.

(c) If an applicant fails to correct the deficiencies, fails to report the corrections by the date specified in the notification of noncompliance, fails to file an appeal of the notification of noncompliance by the date specified, or is unsuccessful in its appeal, the Administrator will provide the applicant with written notification of accreditation denial. An applicant who has received written notification of accreditation denial may apply for accreditation again at any time in accordance with § 205.502.

(d) If the certifying agent was accredited prior to the site evaluation and the certifying agent fails to correct the deficiencies, fails to report the corrections by the date specified in the notification of noncompliance, or fails to file an appeal of the notification of noncompliance by the date specified, the Administrator will begin proceedings to suspend or revoke the certifying agent's accreditation. An applicant who has had its accreditation suspended may apply for accreditation again at any time in accordance with § 205.502. A private entity certifying agent whose accreditation is revoked will be ineligible for accreditation for a period of not less than 3 years following the date of such determination.

§ 205.508 Site evaluations.

(a) Site evaluations of accredited certifying agents shall be conducted for the purpose of examining the certifying agent's operations and evaluating its compliance with the Act and the regulations of this part. Site evaluations shall include an on-site review of the certifying agent's certification procedures, decisions, facilities, administrative and management systems, and production or handling operations certified by the certifying agent. Site evaluations shall be conducted by a representative(s) of the Administrator.

(b) An initial site evaluation of an accreditation applicant shall be conducted before or within a reasonable period of time after issuance of the applicant's "notification of accreditation." A site evaluation shall be conducted after application for renewal of accreditation but prior to the issuance of a notice of renewal of accreditation. One or more site evaluations will be conducted during the period of accreditation to determine whether an accredited certifying agent is complying with the general requirements set forth in § 205.501.

§ 205.509 Peer review panel.

The Administrator may establish a peer review panel to assist in evaluating applicants for accreditation, amendment to an accreditation, and renewal of accreditation as certifying agents. Peer reviewers will serve without compensation.

(a) Peer review panel(s).

(1) A peer review panel shall review the documentation provided by the Administrator after any site evaluation performed pursuant to §§ 205.508 and 205.510.

(2) The Administrator shall consider the reports received from each individual member of a peer review panel when determining whether to continue or renew the accreditation of a certifying agent.

(3) A peer review panel meeting shall be held solely for the purposes of giving and receiving information. Any meeting or conference call shall be conducted in a manner that will ensure the actions of panel members are carried out on an individual basis with any opinions and recommendations by a member being made individually.

(b) Eligibility for peer review panels.

(1) Applicants for membership in the peer review panel pool must:

(i) Provide the Administrator with a written description and, upon request, supporting documentation of their qualifications to conduct peer reviews. Such description must include

information concerning the applicant's training and expertise in organic production or handling methods and in evaluating whether production or handling operations are using a system of organic production or handling.

(ii) Address possible limitations on availability to serve.

(iii) Include information concerning their commercial interests and those of their immediate family members, within the 12-month period prior to application, with any person who may seek to become or who is an accredited certifying agent. No person who has or has had a commercial interest, including an immediate family interest or the provision of consulting services, in an applicant for accreditation or renewal of accreditation within the preceding 12-month period shall be appointed to or accept appointment to a panel evaluating such applicant for accreditation or renewal of accreditation.

(2) Persons accepted to the pool may serve until notified that their appointment has been rescinded by the Administrator or until they are no longer qualified, whichever occurs first.

(c) Composition of peer review panels.

(1) Peer review panels convened by the Administrator shall consist of at least three but no more than five members.

(2) Peer review panels must include:

(i) A Department representative who shall preside over the panel and

(ii) No fewer than two members, drawn from the peer review pool, who possess sufficient expertise, as determined by the Administrator, in the areas of accreditation described in the application for accreditation or the notice of approval of accreditation for each certifying agent whose operations and performance are to be reviewed.

(3) Peer review panels may include:

(i) Up to two members with expertise in other disciplines, including organizational management and finance;

(ii) Member(s) from the approved State organic certification program when the applicant is a private entity that will operate within the State; and

(iii) Member(s) from a foreign government's organic program when the applicant is a private entity that will operate within the country.

(d) Duties and responsibilities of panel members.

(1) Each person on a peer review panel must individually review the site evaluation report prepared by the Department's evaluator(s) and any other information that may be provided by the Administrator relevant to continuing or renewing the accreditation status of a certifying agent;

(2) Information about the certifying agent received as part of the review process is confidential information, and peer reviewers must not release, copy, quote, or otherwise use material from the information received, other than in the report required to be submitted;

(3) Each peer reviewer must agree to treat the information received for review as confidential; and

(4) Each person on a peer review panel must provide an individual written report, including recommendations, to the Administrator regarding a certifying agent's ability to conduct and perform certification activities.

(e) *Peer review panel reports.* Copies of the peer review panel reports will be provided upon request to the certifying agent, and written responses from the certifying agent may be submitted for consideration by the Administrator.

§ 205.510 Annual report, recordkeeping, and renewal of accreditation.

(a) *Annual report and fees.* An accredited certifying agent must submit annually to the Administrator, on or before the anniversary date of the issuance of the notification of accreditation, the following reports and fees:

(1) A complete and accurate update of information submitted pursuant to §§ 205.503 and 205.504;

(2) Information supporting any changes being requested in the areas of accreditation described in § 205.500;

(3) A description of the measures implemented in the previous year and any measures to be implemented in the coming year to satisfy any terms and conditions determined by the Administrator to be necessary, as specified in the most recent notification of accreditation or notice of renewal of accreditation;

(4) The results of the most recent inspector performance appraisals and annual program evaluation and a description of adjustments to the certifying agent's operation and procedures implemented or to be implemented in response to the appraisals and evaluation; and

(5) The fees required in § 205.640(a).

(b) *Recordkeeping.* Certifying agents must maintain records according to the following schedule:

(1) Records obtained from applicants for certification and certified operations must be maintained for not less than 5 years beyond their receipt;

(2) Records created by the certifying agent regarding applicants for certification and certified operations must be maintained for not less than 10 years beyond their creation; and

(3) Records created or received by the certifying agent pursuant to the accreditation requirements of this subpart F, excluding any records covered by §§ 205.510(b)(2), must be maintained for not less than 5 years beyond their creation or receipt.

(c) *Renewal of accreditation.*

(1) An accredited certifying agent's application for accreditation renewal must be received 6 months prior to the fifth anniversary of issuance of the notification of accreditation and each subsequent renewal of accreditation. The accreditation of certifying agents who make timely application for renewal of accreditation will not expire during the renewal process. The accreditation of certifying agents who fail to make timely application for renewal of accreditation will expire as scheduled unless renewed prior to the scheduled expiration date. Certifying agents with an expired accreditation must not perform certification activities under the Act and these regulations.

(2) Following receipt of the information submitted by the certifying agent in accordance with paragraph (a) of this section, the results of a site evaluation, and, if applicable, the reports submitted by a peer review panel, the Administrator will determine whether the certifying agent remains in compliance with the Act and the regulations of this part and should have its accreditation renewed.

(d) *Notice of renewal of accreditation.* Upon a determination that the certifying agent is in compliance with the Act and the regulations of this part, the Administrator will issue a notice of renewal of accreditation. The notice of renewal will specify any terms and conditions that must be addressed by the certifying agent and the time within which those terms and conditions must be satisfied.

(e) *Noncompliance.* Upon a determination that the certifying agent is not in compliance with the Act and the regulations of this part, the Administrator will initiate proceedings to suspend or revoke the certifying agent's accreditation.

§§ 205.511—205.599 [Reserved]

Subpart G—Administrative

The National List of Allowed and Prohibited Substances

§ 205.600 Allowed and prohibited substances and ingredients in organic production and handling.

To be sold or labeled as "organic," or "made with organic (specified ingredients)," the product must be

produced and handled without the use of:

(a) Synthetic substances and ingredients, except as provided in § 205.601 and § 205.603.

(b) Nonagricultural substances used in or on processed products, except as otherwise provided in § 205.605;

(c) Nonsynthetic substances prohibited in § 205.602 or § 205.604; and

(d) Materials, processes, or techniques prohibited in § 205.301.

§ 205.601 Synthetic substances allowed for use in organic crop production.

In accordance with restrictions specified in this section and § 205.102 and § 205.200 through § 205.207, the following synthetic substances may be used:

(a) As algicides, disinfectants and sanitizers, including irrigation system cleaning systems

(1) Alcohols

(i) Ethanol

(ii) Isopropanol

(2) Chlorine Materials—*Except*, That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

(i) Calcium Hypochlorite

(ii) Chlorine Dioxide

(iii) Sodium Hypochlorite

(3) Hydrogen Peroxide

(4) Soap-Based Algicides/Demossers

(b) As herbicides, weed barriers, as applicable.

(1) Herbicides, Soap-Based—for use in farmstead maintenance (roadways, ditches, right of ways, building perimeters) and ornamental crops

(2) Mulches

(i) Newspaper or other recycled paper, without glossy or colored inks.

(ii) Plastic mulch and covers (petroleum-based other than polyvinyl chloride (PVC))

(c) As compost feedstocks—Newspapers or other recycled paper, without glossy or colored inks

(d) As animal repellents—Soaps, Ammonium—for use as a large animal repellent only, no contact with soil or edible portion of crop

(e) As insecticides (including acaricides or mite control)

(1) Ammonium Carbonate—for use as bait in insect traps only, no direct contact with crop or soil

(2) Boric Acid—structural pest control, no direct contact with organic food or crops

(3) Elemental Sulfur

(4) Lime Sulfur—including calcium polysulfide, fungicides, or insecticides if no alternatives

(5) Oils, Horticultural—as dormant, suffocating, and summer oils

(6) Petroleum-Based Oils—on woody plants for dormant and summer pest control, *Except*, That, a petroleum-based material allowed as a pesticide is prohibited for use as a herbicide. Aromatic petroleum solvents as a subclass of petroleum-based oils are prohibited.

(7) Soaps, Insecticidal

(8) Sticky Traps/Barriers

(f) As insect attractants—Pheromones

(g) As rodenticides

(1) Sulfur Dioxide—underground rodent control only (smoke bombs)

(2) Vitamin D3

(h) As slug or snail bait—[Reserved]

(i) As plant disease control

(1) Coppers, Fixed—Copper

Hydroxide, Copper Oxide, Copper Oxychloride, Includes products exempted from EPA tolerance, *Except*, That, copper-based materials shall be managed in a way that prevents excessive accumulation in the soil and shall not be used as herbicides.

(2) Copper Sulfate—Substance must be used in a manner that minimizes accumulation of copper in the soil.

(3) Hydrated Lime—not permitted for soil application or to cauterize mutilations or deodorize animal wastes

(4) Hydrogen Peroxide

(5) Oils, Horticultural, as dormant, suffocating, and summer oils, insecticides only

(6) Petroleum-Based Oils—*Except*, That, aromatic petroleum solvents as a subclass of petroleum-based oils are prohibited.

(7) Potassium Bicarbonate

(8) Elemental Sulfur

(j) As plant or soil amendments.

(1) Aquatic Plant Extracts (other than hydrolyzed)—Extraction process is limited to the use of Potassium Hydroxide or Sodium Hydroxide; solvent amount used is limited to that amount necessary for extraction.

(2) Humic Acids—naturally occurring deposits, water and alkali extracts only

(3) Lignin Sulfonate—chelating agent, dust suppressant, floatation agent

(4) Micronutrients—not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Soil deficiency must be documented by soil or tissue test.

(i) Soluble Boron Products

(ii) Sulfates, carbonates, oxides, or silicates of zinc, iron, magnesium, manganese, molybdenum, selenium, and cobalt

(5) Liquid Fish Products—can be pH adjusted with sulfuric, citric or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5

(6) Vitamins, B1, C, and E

(k) As plant growth regulators—[Reserved]

(l) As floating agents in postharvest handling

(1) Lignin Sulfonate

(2) Sodium Silicate—for tree fruit and fiber processing

(m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with a synthetic substance listed in this section and used as an active ingredient in accordance with any limitations on the use of such synthetic substances—EPA List 4—Inerts of Minimal Concern

(n)–(z) [Reserved]

§ 205.602 Nonsynthetic substances prohibited for use in organic crop production.

(a) Ash from manure burning

(b) Arsenic

(c) Lead salts

(d) Sodium Fluoroaluminate (Mined)

(e) Strychnine

(f) Tobacco Dust

(g)–(z) [Reserved]

§ 205.603 Synthetic substances allowed for use in organic livestock production.

Any substance in the following categories may be used in organic livestock production in accordance with any restrictions specified in this section and § 205.102 and § 205.236 through § 205.239.

(a) As disinfectants, sanitizers, and medical treatments as applicable

(1) Alcohols

(i) Ethanol—disinfectant and sanitizer only, prohibited as a feed additive

(ii) Isopropanol—disinfectant only

(2) Aspirin—approved for health care use to reduce inflammation

(3) Chlorine Materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act

(i) Calcium Hypochlorite

(ii) Chlorine Dioxide

(iii) Sodium Hypochlorite

(4) Chlorhexidine—Allowed for surgical procedures conducted by a veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness

(5) Electrolytes—without antibiotics

(6) Glucose

(7) Glycerin—Allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils

(8) Iodine

(9) Hydrogen Peroxide

(10) Magnesium Sulfate

(11) Parasiticides—Ivermectin—Prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system

plan-approved preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic

(12) Phosphoric Acid—allowed as an equipment cleaner

(13) Vaccines and Biologics

(b) As topical treatment, external parasiticide or local anesthetic as applicable.

(1) Iodine

(2) Lidocaine—as a local anesthetic.

Use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals

(3) Lime, Hydrated—(Bordeaux mixes)

(4) Mineral Oil—for topical use and as a lubricant

(5) Procaine—as a local anesthetic, use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals

(6) Copper Sulfate

(c) As feed supplements—Milk Replacers—without antibiotics, as emergency use only, no nonmilk products or products from BST treated animals

(d) As feed additives

(1) Trace Minerals, including:

(i) Copper Sulfate

(ii) Magnesium Sulfate

(2) Vitamins—accepted for enrichment or fortification, limited to those approved by the FDA for livestock use

(e) As fillers and excipients

(f)–(z) [Reserved]

§ 205.604 Nonsynthetic substances prohibited for use in organic livestock production. [Reserved]

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients).”

The following nonagricultural substances may be used only in accordance with any restrictions specified in this section and § 205.102, § 205.270, and § 205.300 through § 205.310.

(a) *Nonsynthetics allowed:*

(1) Agar-agar

(2) Acids

(i) Alginic

(ii) Citric—produced by microbial fermentation of carbohydrate substances

(iii) Lactic

(3) Baking Powder—aluminum-free

(4) Bentonite

(5) Calcium Carbonate

(6) Calcium Chloride

(7) Carrageenan

(8) Cornstarch (Native)

(9) Dairy Cultures—non-EM

(10) Diatomaceous Earth—food

filtering aid only

(11) Enzymes—must be derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria

(12) Gums—Water extracted only (arabic, guar, locust bean, carob bean)

(13) Kaolin

(14) Kelp—for use only as a thickener and dietary supplement

(15) Lecithin—unbleached

(16) Nitrogen—Oil-free grades

(17) Oxygen—Oil-free grades

(18) Pectin (high-methoxy)

(19) Perlite—for use only as a filter aid in food processing

(20) Potassium Chloride

(21) Potassium Iodide

(22) Sodium Bicarbonate

(23) Sodium Carbonate

(24) Yeast—Nonsynthetic, non-EM

(i) Autolysate

(ii) Bakers

(iii) Brewers

(iv) Nutritional

(v) Smoked—growth on petrochemical substrate and sulfite waste liquor prohibited. Nonsynthetic smoke flavoring process must be documented

(b) *Synthetics allowed:*

(1) Alginates

(2) Ammonium Bicarbonate—for use only as a leavening agent

(3) Ammonium Carbonate—for use only as a leavening agent

(4) Ascorbic Acid

(5) Calcium Citrate

(6) Calcium Hydroxide

(7) Calcium Phosphates (monobasic and dibasic)

(8) Carbon Dioxide

(9) Chlorine Materials—disinfecting and sanitizing food contact surfaces, *Except*, That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

(i) Calcium Hypochlorite

(ii) Chlorine Dioxide

(iii) Sodium Hypochlorite

(10) Ethylene—allowed for post harvest ripening of tropical fruit

(11) Ferrous Sulfate—for iron enrichment or fortification of foods when required by regulation or recommended (independent organization)

(12) Glycerides (mono and di)—for use only in drum drying of food

(13) Glycerin—produced by hydrolysis of fats and oils

(14) Hydrogen peroxide

- (15) Lecithin—bleached
- (16) Magnesium Carbonate—for use only in agricultural products labeled “made with organic (specified ingredients),” prohibited in agricultural products labeled “organic”
- (17) Magnesium Chloride—derived from sea water
- (18) Magnesium Stearate—for use only in agricultural products labeled “made with organic (specified ingredients),” prohibited in agricultural products labeled “organic”
- (19) Magnesium Sulfate
- (20) Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods
- (21) Ozone
- (22) Pectin (low-methoxy)
- (23) Phosphoric Acid—cleaning of food-contact surfaces and equipment only
- (24) Potassium Acid Tartrate
- (25) Potassium Tartrate made from Tartaric acid
- (26) Potassium Carbonate
- (27) Potassium Citrate
- (28) Potassium Hydroxide—prohibited for use in lye peeling of fruits and vegetables
- (29) Potassium Iodide—for use only in agricultural products labeled “made with organic (specified ingredients),” prohibited in agricultural products labeled “organic”
- (30) Potassium Phosphate—for use only in agricultural products labeled “made with organic (specific ingredients),” prohibited in agricultural products labeled “organic”
- (31) Silicon Dioxide
- (32) Sodium Citrate
- (33) Sodium Hydroxide—prohibited for use in lye peeling of fruits and vegetables
- (34) Sodium Phosphates—for use only in dairy foods
- (35) Tocopherols—derived from vegetable oil when rosemary extracts are not a suitable alternative
- (36) Xanthan gum
- (c)–(z) [Reserved]

§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as organic or made with organic ingredients.

Any nonorganically produced agricultural product may be used in accordance with any restrictions specified in this section and § 205.102, § 205.270, and § 205.300 through § 205.310.

§ 205.607 Amending the National List.

(a) Any person may petition the National Organic Standard Board for the purpose of having a substance evaluated

for recommendation to the Secretary for inclusion on or deletion from the National List in accordance with section 6517 of the Act.

(b) A person petitioning for amendment of the National List should request a copy of the petition procedures from the USDA at the address in § 205.607(c).

(c) A petition to amend the National List must be submitted to: Program Manager, USDA/AMS/TM/NOP, Room 2945 South Building, PO Box 96456, Washington, DC 20090–6456.

(d) A substance may be added to the National List only in the following categories:

(1) Synthetic substances allowed for use in organic crop or livestock production;

(2) Nonsynthetic substances prohibited for use in organic crop or livestock production; or

(3) Nonagricultural substances allowed for use as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients).”

State Programs

§ 205.620 Requirements of State organic certification programs.

(a) A State may establish a State organic certification program for production and handling operations within the State which produces and handles organic agricultural products.

(b) A State organic certification program must meet the general requirements for organic programs specified in the Act and be at least equivalent to the regulations in this part.

(c) A State organic certification program may contain more restrictive requirements based on unique environmental conditions or specific production or handling practices particular to the State or region of the United States, which necessitates the more restrictive requirement. Such additional requirements must further the purposes and be consistent with the Act and regulations in this part.

(d) A State organic certification program must assume enforcement obligations in the State for the requirements of this part and any more restrictive requirements approved by the Secretary.

(e) A State organic certification program and any amendments to such program must be approved by the Secretary prior to being implemented by the State.

§ 205.621 Submission and determination of proposed State organic certification programs and amendments to approved State organic certification programs.

(a) A State program’s governing State official must submit to the Secretary a proposed State organic certification program and any proposed amendments to such approved program.

(1) Such submission must contain supporting materials that include statutory authorities, program description, a statement of acceptance of the general requirements for organic programs specified in the Act, documentation of unique environmental or ecological conditions or specific production practices particular to the State which necessitate more restrictive requirements than the requirements of this part, and other information as may be required by the Secretary.

(2) Submission of a request for amendment of an approved State organic certification program must contain supporting material that includes an explanation and documentation of the unique environmental or ecological conditions or specific production practices particular to the State or region, which necessitates the proposed amendment. Supporting material also must explain how the proposed amendment furthers and is consistent with the purposes of the Act and the regulations of this part.

(b) Within 6 months of receipt of submission, the Secretary will:

(1) Publish in the **Federal Register** for public comment, a summary of a proposed State organic certification program, and a summary of any proposed amendment to such program.

(2) After review of materials and documentation accompanying the proposal and consideration of comments received, notify the State program’s governing State official of approval or disapproval of the proposed program or amendment of an approved program and, if disapproved, the reasons for the disapproval.

(c) After receipt of a notice of disapproval, the State program’s governing State official may resubmit a revised State organic certification program or amendment of such a program at any time.

§ 205.622 Review of approved State organic certification programs.

The Secretary will review a State organic certification program not less than once during each 5-year period following the date of the initial program approval. The Secretary will notify the State program’s governing State official of approval or disapproval of the

program within 6 months after initiation of the review.

Fees

§ 205.640 Fees and other charges for accreditation.

Fees and other charges equal as nearly as may be to the cost of the accreditation services rendered under the regulations, including initial accreditation, review of annual reports, and renewal of accreditation, shall be assessed and collected from applicants for initial accreditation and accredited certifying agents submitting annual reports or seeking renewal of accreditation in accordance with the following provisions.

(a) *Fees-for-Service.*

(1) Except as otherwise provided in this section, fees-for-service shall be based on the time required to render the service provided calculated to the nearest 15-minute period, including the review of applications and accompanying documents and information, evaluator travel, the conduct of on-site evaluations, review of annual reports and updated documents and information, and the time required to prepare reports and any other documents in connection with the performance of service. The hourly rate shall be the same as that charged by the Agricultural Marketing Service (AMS), through its Quality Systems Certification Program, to certification bodies requesting conformity assessment to the International Organization for Standardization "General Requirements for Bodies Operating Product Certification Systems" (ISO Guide 65).

(2) Applicants for initial accreditation and accredited certifying agents submitting annual reports or seeking renewal of accreditation during the first 18 months following the effective date of subpart F of this part shall receive service without incurring an hourly charge for service.

(3) Applicants for initial accreditation and renewal of accreditation must pay at the time of application, effective 18 months following the effective date of subpart F of this part, a nonrefundable fee of \$500.00 which shall be applied to the applicant's fees-for-service account.

(b) *Travel charges.* When service is requested at a place so distant from the evaluator's headquarters that a total of one-half hour or more is required for the evaluator(s) to travel to such place and back to the headquarters or at a place of prior assignment on circuitous routing requiring a total of one-half hour or more to travel to the next place of assignment on the circuitous routing,

the charge for such service shall include a mileage charge administratively determined by the Department and travel tolls, if applicable, or such travel prorated among all the applicants and certifying agents furnished the service involved on an equitable basis or, where the travel is made by public transportation (including hired vehicles), a fee equal to the actual cost thereof. Travel charges shall become effective for all applicants for initial accreditation and accredited certifying agents on the effective date of subpart F of this part. The applicant or certifying agent will not be charged a new mileage rate without notification before the service is rendered.

(c) *Per diem charges.* When service is requested at a place away from the evaluator's headquarters, the fee for such service shall include a per diem charge if the employee(s) performing the service is paid per diem in accordance with existing travel regulations. Per diem charges to applicants and certifying agents will cover the same period of time for which the evaluator(s) receives per diem reimbursement. The per diem rate will be administratively determined by the Department. Per diem charges shall become effective, for all applicants for initial accreditation and accredited certifying agents on the effective date of subpart F of this part. The applicant or certifying agent will not be charged a new per diem rate without notification before the service is rendered.

(d) *Other costs.* When costs, other than costs specified in paragraphs (a), (b), and (c) of this section are associated with providing the services, the applicant or certifying agent will be charged for these costs. Such costs include, but are not limited to, equipment rental, photocopying, delivery, facsimile, telephone, or translation charges incurred in association with accreditation services. The amount of the costs charged will be determined administratively by the Department. Such costs shall become effective for all applicants for initial accreditation and accredited certifying agents on the effective date of subpart F of this part.

§ 205.641 Payment of fees and other charges.

(a) Applicants for initial accreditation and renewal of accreditation must remit the nonrefundable fee, pursuant to § 205.640(a)(3), along with their application. Remittance must be made payable to the Agricultural Marketing Service, USDA, and mailed to: Program Manager, USDA-AMS-TMP-NOP, Room 2945-South Building, PO Box

96456, Washington, DC 20090-6456 or such other address as required by the Program Manager.

(b) Payments for fees and other charges not covered under paragraph (a) of this section must be:

(1) Received by the due date shown on the bill for collection;

(2) Made payable to the Agricultural Marketing Service, USDA; and

(3) Mailed to the address provided on the bill for collection.

(c) The Administrator shall assess interest, penalties, and administrative costs on debts not paid by the due date shown on a bill for collection and collect delinquent debts or refer such debts to the Department of Justice for litigation.

§ 205.642 Fees and other charges for certification.

Fees charged by a certifying agent must be reasonable, and a certifying agent shall charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator. The certifying agent shall provide each applicant with an estimate of the total cost of certification and an estimate of the annual cost of updating the certification. The certifying agent may require applicants for certification to pay at the time of application a nonrefundable fee of no more than \$250.00, which shall be applied to the applicant's fees-for-service account. The certifying agent shall provide all persons inquiring about the application process with a copy of its fee schedule.

§§ 205.643–205.649 [Reserved]

Compliance

§ 205.660 General.

(a) The National Organic Program's Program Manager, on behalf of the Secretary, may inspect and review certified production and handling operations and accredited certifying agents for compliance with the Act or regulations in this part.

(b) The Program Manager may initiate suspension or revocation proceedings against a certified operation:

(1) When the Secretary has reason to believe that a certified operation has violated or is not in compliance with the Act or regulations in this part.

(2) When a certifying agent or a State program's governing State official fails to take appropriate action to enforce the Act or regulations in this part; or

(c) The Program Manager may initiate suspension or revocation of a certifying agent's accreditation if the certifying agent fails to meet, conduct, or maintain

accreditation requirements pursuant to the Act or this part.

§ 205.661 Investigation of certified operations.

(a) A certifying agent may investigate complaints of noncompliance with the Act or regulations of this part concerning production and handling operations certified as organic by the certifying agent. A certifying agent must notify the Program Manager of all compliance proceedings and actions taken pursuant to this part.

(b) A State program's governing State official may investigate complaints of noncompliance with the Act or regulations in this part concerning organic production or handling operations operating in the State.

§ 205.662 Noncompliance procedure for certified operations.

(a) *Notification.* When an inspection, review, or investigation of a certified operation by a certifying agent or a State program's governing State official reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation. Such notification shall provide:

(1) A description of each noncompliance;

(2) The facts upon which the notification of noncompliance is based; and

(3) The date by which the certified operation must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible.

(b) *Resolution.* When a certified operation demonstrates that each noncompliance has been resolved, the certifying agent or the State program's governing State official, as applicable, will send the certified operation a written notification of noncompliance resolution.

(c) *Proposed suspension or revocation.* When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period or is not adequate to demonstrate that each noncompliance has been corrected, the certifying agent or State program's governing State official shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance. When correction of a noncompliance is not possible, the notification of noncompliance and the proposed suspension or revocation of certification may be combined in one notification. The notification of

proposed suspension or revocation of certification shall state:

(1) The reasons for the proposed suspension or revocation;

(2) The proposed effective date of such suspension or revocation;

(3) The impact of a suspension or revocation on future eligibility for certification; and

(4) The right to request mediation pursuant to § 205.663 or to file an appeal pursuant to § 205.681.

(d) *Willfull violations.*

Notwithstanding paragraph (a) of this section, if a certifying agent or State program's governing State official has reason to believe that a certified operation has willfully violated the Act or regulations in this part, the certifying agent or State program's governing State official shall send the certified operation a notification of proposed suspension or revocation of certification of the entire operation, or a portion of the operation, as applicable to the noncompliance.

(e) *Suspension or revocation.*

(1) If the certified operation fails to correct the noncompliance, to resolve the issue through rebuttal or mediation, or to file an appeal of the proposed suspension or revocation of certification, the certifying agent or State program's governing State official shall send the certified operation a written notification of suspension or revocation.

(2) A certifying agent or State program's governing State official must not send a notification of suspension or revocation to a certified operation that has requested mediation pursuant to § 205.663 or filed an appeal pursuant to § 205.681.

(f) *Ineligibility.* A certified operation or a person responsibly connected with an operation whose certification has been revoked will not be eligible to receive certification for a period of not more than 5 years following the date of such revocation, as determined by the Secretary.

§ 205.663 Mediation.

Any dispute with respect to proposed suspension or revocation of certification under this part shall, at the request of the applicant for certification or certified operation, be mediated by a qualified mediator mutually agreed upon by the parties to the mediation. If a State Program is in effect, the mediation procedures established in the State Program, as approved by the Secretary, will be followed. Mediation shall be requested in writing to the applicable certifying agent. The parties to the mediation shall have no more than 30 days to reach an agreement following a mediation session. If

mediation is unsuccessful, the applicant for certification or certified operation shall have 30 days from termination of mediation to appeal the certifying agent's decision to the Administrator, pursuant to § 205.681. Any agreement reached during or as a result of the mediation process shall be in compliance with the Act and these regulations. The Secretary may review any mediated agreement for conformity to the Act and these regulations.

§ 205.664 [Reserved]

§ 205.665 Noncompliance procedure for certifying agents.

(a) *Noncompliance.* When an inspection, review, or investigation of an accredited certifying agent by the Program Manager reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certifying agent, as applicable. Such notification shall provide:

(1) A description of each noncompliance found;

(2) The facts upon which the notification of noncompliance is based; and

(3) The date by which the certifying agent must rebut or correct each noncompliance when correction is possible.

(b) *Resolution.* When each noncompliance has been resolved, the Program Manager shall send the certifying agent a written notification of noncompliance resolution.

(c) *Proposed suspension or revocation.* If rebuttal is unsuccessful or if correction of the noncompliance is not made within the prescribed time period or is not adequate to demonstrate that each noncompliance has been corrected, the Program Manager shall send a written notification of proposed suspension or revocation of accreditation to the certifying agent. The notification of proposed suspension or revocation shall state whether the certifying agent's accreditation or specified areas of accreditation are to be suspended or revoked. When correction of a noncompliance is not possible, the notification of noncompliance and the proposed suspension or revocation may be combined in one notification. The notification of proposed suspension or revocation of accreditation shall state:

(1) The reasons for the proposed suspension or revocation;

(2) The proposed effective date of the suspension or revocation;

(3) The impact of a suspension or revocation on future eligibility for accreditation; and

(4) The right to file an appeal pursuant to § 205.681.

(d) Willful violations.

Notwithstanding paragraph (a) of this section, if the Program Manager has reason to believe that a certifying agent has willfully violated the Act or regulations in this part, the Program Manager shall send a written notification of proposed suspension or revocation of accreditation to the certifying agent.

(e) Suspension or revocation. When the accredited certifying agent fails to file an appeal of the proposed suspension or revocation of accreditation, the Program Manager shall send a written notice of suspension or revocation of accreditation to the certifying agent.

(f) Cessation of certification activities. A certifying agent whose accreditation is suspended or revoked must:

(1) Cease all certification activities in each area of accreditation which its accreditation is suspended or revoked.

(2) Transfer to the Secretary and make available to any applicable governing State official all records concerning its certification activities that were suspended or revoked.

(g) Eligibility.

(1) A certifying agent whose accreditation is suspended by the Secretary under this section may at any time submit a new request for accreditation, pursuant to § 205.502. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part.

(2) A certifying agent whose accreditation is revoked by the Secretary shall be ineligible to be accredited as a certifying agent under the Act and the regulations in this part for a period of not less than 3 years following the date of such revocation.

§§ 205.666 and 205.667 [Reserved]

§ 205.668 Noncompliance procedures under State organic certification programs.

(a) A State program's governing State official must promptly notify the Secretary of commencement of any enforcement proceeding against a certified operation and forward to the Secretary a copy of each notice issued.

(b) A noncompliance proceeding, brought by a State program's governing State official against a certified operation, shall be appealable pursuant to the appeal procedures of the State organic certification program. There shall be no subsequent rights of appeal to the Secretary. Final decisions of a

State may be appealed to the United States District Court for the district in which such certified operation is located.

(c) A State program's governing State official may review and investigate complaints of noncompliance with the Act or regulations concerning accreditation of certifying agents operating in the State. When such review or investigation reveals any noncompliance, the State program's governing State official shall send a written report of noncompliance to the Program Manager. The report shall provide a description of each noncompliance and the facts upon which the notification of noncompliance is based.

§ 205.669 [Reserved]

Inspection and Testing, Reporting, and Exclusion from Sale

§ 205.670 Inspection and testing of agricultural product to be sold or labeled organic.

(a) All agricultural products that are to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients)" must be made accessible by certified organic production or handling operations for examination by the Administrator, the applicable State program's governing State official, or the certifying agent.

(b) The Administrator, applicable State program's governing State official, or the certifying agent may require preharvest or postharvest testing of any agricultural input used or agricultural product to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients)" when there is reasonable cause to believe that the agricultural input or product has come into contact with a prohibited substance. Such tests must be conducted by the applicable State program's governing State official or the certifying agent at the official's or certifying agent's own expense.

(c) The preharvest or postharvest tissue test sample collection pursuant to paragraph (b) of this section must be performed by an inspector representing the Administrator, certifying agent, or applicable State program's governing State official. Sample integrity must be maintained in transit, and residue testing must be performed in an accredited laboratory. Chemical analysis must be made in accordance with the methods described in the 16th edition of the *Official Methods of Analysis of the AOAC International* or other applicable validated methodology determining the

presence of contaminants in agricultural products.

(d) Results of all analyses and tests performed under this section:

(1) Must be provided to the Administrator promptly upon receipt; and

(2) Will be available for public access, unless the testing is part of an ongoing compliance investigation.

§ 205.671 Exclusion from organic sale.

(a) When residue testing detects prohibited substances at levels that are greater than the estimated national mean of detected residues for specific commodity/pesticide pairs, as demonstrated by USDA's Pesticide Data Program, or unavoidable residual environmental contamination, as determined by the Administrator, the agricultural product must not be sold, labeled, or represented as organically produced. The Administrator, the applicable State program's governing State official, or the certifying agent may conduct an investigation of the certified operation to determine the cause of the prohibited substance residue.

(b) If test results indicate a specific agricultural product contains pesticide residues or environmental contaminants that exceed the Food and Drug Administration's or the Environmental Protection Agency's regulatory tolerances, the data must be reported promptly to the appropriate public health agencies.

§ 205.672 Emergency pest or disease treatment.

When a prohibited substance is applied to a certified operation due to Federal or State emergency pest eradication or disease treatment program and the certified operation otherwise meets the requirements of this part, the certification status of the operation shall not be affected as a result of the application of the prohibited synthetic substance: *Provided, That:*

(a) Any harvested crop or plant part to be harvested that has contact with a prohibited substance applied as the result of a Federal or State emergency pest eradication or disease treatment program cannot not be sold, labeled, or represented as organically produced; and

(b) Any livestock that are treated with a prohibited substance applied as the result of a Federal or State emergency pest or disease treatment program or product derived from such treated livestock cannot be sold, labeled, or represented as organically produced: *Except, That:*

(1) Milk or milk products may be sold, labeled, or represented as organically

produced beginning 12 months following the last date that the dairy animal was treated with the prohibited substance; and

(2) The offspring of gestating mammalian breeder stock treated with a prohibited substance may be considered organic: *Provided*, That, the breeder stock was not in the last third of gestation on the date that the breeder stock was treated with the prohibited substance.

§§ 205.673—205.679 [Reserved]

Adverse Action Appeal Process

§ 205.680 General.

Persons subject to the Act who believe they are adversely affected by a noncompliance proceeding decision of the National Organic Program's Program Manager or a certifying agent may appeal such decision to the Administrator.

§ 205.681 Appeals.

(a) *Certification appeals.* An applicant for certification may appeal a certifying agent's notice of denial of certification, and a certified operation may appeal a certifying agent's notification of proposed suspension or revocation of certification to the Administrator: *Except*, That, when the applicant or certified operation is subject to an approved State organic certification program and the decision to deny, suspend, or revoke a certification is made by a certifying agent or a State program's governing State official, the appeal must be made to the State program's governing State official or such official's designee who will carry out the appeal pursuant to the State program's appeal procedures approved by the Secretary.

(1) If the Administrator sustains a certification applicant's or certified operation's appeal of a certifying agent's decision, the applicant will be issued organic certification, or a certified operation will continue its certification, as applicable to the operation. The act of sustaining the appeal shall not be an adverse action subject to appeal by the affected certifying agent.

(2) If the Administrator denies an appeal, a formal administrative proceeding will be initiated to deny, suspend, or revoke the certification. Such proceeding shall be conducted pursuant to the Department's Uniform Rules of Practice.

(b) *Accreditation appeals.* An applicant for accreditation and an accredited certifying agent may appeal a Program Manager's denial of accreditation or proposed suspension or

revocation of accreditation to the Administrator.

(1) If the Administrator sustains an appeal, an applicant will be issued accreditation, or a certifying agent will continue its accreditation, as applicable to the operation.

(2) If the Administrator denies an appeal, a formal administrative proceeding to deny, suspend, or revoke the accreditation will be initiated. Such proceeding shall be conducted pursuant to the Department's Uniform Rules of Practice.

(c) An appeal of a noncompliance decision must be filed within the time period provided in the letter of notification or at least 30 days from the receipt of the notification. The appeal will be considered "filed" on the date received by the Administrator or by the State program's governing State official or such official's designee as provided in the State's approved appeal procedures. A decision to deny, suspend, or revoke certification or accreditation will become final and nonappealable unless the decision is appealed in a timely manner.

(d) All appeals to the Administrator must be filed in writing and addressed to Administrator, USDA-AMS, Room 3071-S, PO Box 96456, Washington, DC 20090-6456, and be copied to the certifying agent completely and simultaneously with submission to the Administrator. Appeals must include a copy of the adverse decision and a statement of the appellant's position that the decision was not made in accordance with applicable program regulations, policies, or procedures.

§§ 205.682—205.689 [Reserved].

Miscellaneous

§ 205.690 OMB control number.

The control number assigned to the information collection requirements by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1980, Public Law 96-511, is OMB number 0581-0181.

§§ 205.691—205.699 [Reserved]

PARTS 206–209—[RESERVED]

Dated: March 3, 2000.

Kathleen A. Merrigan,
Administrator, Agricultural Marketing Service.

Appendices to the Preamble

Appendix A.—Regulatory Impact Assessment for Proposed Rules Implementing the Organic Foods Production Act of 1990 (Executive Order 12866)

The following regulatory assessment is provided to fulfill the requirements of Executive Order 12866. This assessment consists of a statement of the need for the proposed action, a description of the baseline for the analysis, an examination of alternative approaches, and an analysis of the benefits and costs. Much of the analysis is necessarily descriptive of the anticipated effects of the proposed rule. Because basic market data on the prices and quantities of organic goods and services and the costs of organic production are limited, it is not possible to provide quantitative estimates of all benefits and costs of the proposed rule. The cost of fees and recordkeeping proposed by U.S. Department of Agriculture (USDA) are quantified, but the anticipated benefits are not. Consequently, the analysis does not estimate the magnitude or the direction (positive or negative) of net benefits.

The Need for the Proposed Action

The Organic Foods Production Act of 1990, Title XXI of the Food, Agriculture, Conservation and Trade Act of 1990, U.S.C. Title 7, mandates that the Secretary of Agriculture develop a national organic program. The OFPA states that the Secretary shall establish an organic certification program for farmers, wild-crop harvesters, and handlers of agricultural products that have been produced using organic methods as provided for in the OFPA. In addition, section 6514 of the OFPA requires the Secretary to establish and implement a program to accredit a State program's governing State official or any private person, who meets the requirements of the Act, as a certifying agent to certify that farm, wild-crop harvesting, or handling operations are in compliance with the standards set out in the regulation. As stated by the OFPA in section 6501, the regulations are proposed for the following purposes: (1) to establish national standards governing the marketing of certain agricultural products as organically produced products; (2) to assure consumers that organically produced products meet a consistent standard; and (3) to facilitate interstate commerce in fresh and processed food that is organically produced.

The OFPA was introduced at the request of the organic community after it experienced a number of problems in the marketing of organic products. Many consumers are willing to pay price premiums for organic food; hence, producers (farmers, ranchers, and wild-crop harvesters) and handlers have an economic incentive to label their products

organic. Because organic products cannot be distinguished from conventionally produced products by sight inspection, consumers rely on verification methods, such as certification by private entities or verification by retailers to ensure that organic claims are true. Where there has been no mandatory certification, consumers have been unable to verify organic product claims on their own, and may have been vulnerable to fraud from the mislabeling of organic products.

As organic production became better established in the 1980's, new certifying agencies were formed, and some States passed laws establishing standards for organic production. However, the standards for organic production, processing, handling, and labeling were different to some degree, causing disagreements between certifying agents over whose standards would apply to ingredients used in multi-ingredient organic processed products. Disagreements about standards also created sourcing problems for handlers of these multiingredient products.

Certifying agents are able to negotiate and maintain reciprocity agreements at some cost. These reciprocity agreements specify the conditions under which certifying agents recognize each others' standards. The current system of variable standards has led the organic industry to take on costs of private accreditation or shipment-by-shipment certification, required to gain access to some foreign markets such as the European Union (EU). These costs would be avoided if a national program were in place.

Baseline

The organic industry is characterized by an array of production and handling practices, self regulation and state regulation, and consumer perceptions. However, there are commonalities throughout the industry.

Certification

The United States currently has 49 certifying agents. There are 36 private certifying agencies and 13 States which have certification programs. Private certifying agents range from small nonprofit associations that certify only a few growers to large for-profit businesses operating in numerous States and certifying hundreds of producers. Typically, certifying agents review producers' organic production plans, inspect the farm fields and facilities to be certified, periodically reinspect, and may conduct soil tests and tests for residues of prohibited substances. In some cases, certifying agents negotiate reciprocity agreements with other agents.

State laws vary widely on organic certification and registration. Some States require only that an organic producer register and make certification voluntary. California is an example. Other States require certification by the State's own agents, while others accept certification by a private certifying agent. The least stringent requirement among States with organic legislation is that products marketed as organic comply with their definition of organic but both registration and certification are voluntary. Approximately half of the States have laws which regulate organic production and processing. Thirteen States

operate programs to certify organic production. In many States producers may claim their product is organic but operate without certification or well-defined standards. On the other hand, many organic producers operate in States with no program and voluntarily secure third party certification to well-defined standards. Certification costs vary with farm size and across certifying agents. Illustrative certification costs are presented in Tables 2A and 2B.

Very few certifying agents operate with an external accreditation. There is no law which requires them to be accredited: The price may be unacceptably high in relation to expected benefits; the certifying agent may be unable to find an accrediting party willing to accredit the particular organic program the certifying agent is marketing; and State programs may believe that their status as a government entity obviates the need for external accreditation.

In 1999 USDA began verifying certifying agents to International Organization for Standardization (ISO) Guide 65. It is a valuable recognition that the certifying entity satisfies the business capacity standards of ISO Guide 65. European Union authorities have accepted verification of certifying agents to ISO Guide 65 as an interim measure to facilitate exports pending the establishment of a national organic program.

Organic Food Production

Organic production occurs in all States. An estimated 12,000 organic producers are operating in the United States. Most organic producers are small both in terms of value of sales and acreage. Small producers do not necessarily farm full-time, and may not depend solely on farm income for a livelihood. Some organic production occurs as a distinct part of a larger operation that includes conventional production practices.

Key production practices followed by certified organic producers include: abstaining from use of certain crop chemicals and animal drugs; ecologically based pest and nutrient management; segregation of organic fields and animals from nonorganic fields and animals; following an organic production plan with multiple goals, including sustainability; and record keeping to document practices and progress toward the plan's goals. Specific elements of organic production will vary, but organic systems generally share a core set of practices. For example, the certification standards of virtually all State and private U.S. certifying agents prohibit the use synthetic chemical herbicides and insecticides or animal growth hormones. And most certification standards include a three year ban on the use of prohibited substances on cropland before production can be certified as organic.

On the other hand, certification standards for organic livestock production have been more variable, for pasture, feed, and other practices. Until 1999, the USDA Food Safety and Inspection Service (FSIS) withheld approval for the use of organic labels on meat and poultry products pending the outcome of this rulemaking. However, the Secretary announced a change in policy in January 1999. Meat and poultry products may be

labeled "certified organic by (name of the certifying agent)" if processors obtain prior label approval from FSIS and the claim meets certain basic criteria. However, many private and State certifying programs have not developed standards for livestock production.

The provisions of the New Hampshire organic program are summarized below to illustrate key elements of current organic standards. The New Hampshire program provisions are not substantially different from provisions in some State programs, private programs, and mirror provisions of USDA's proposed national program. Soil tests are required for initial certification and every three years afterward. Soil testing measures the quality of the soil for agricultural production and is different from residue testing. New Hampshire requires residue testing "if the department believes that the produce or soil which certified produce was grown may have become contaminated with prohibited substances." (New Hampshire Rule AGR 906 Certification of Organically Grown Food, Agr 906.05 Laboratory Analysis) Other production standards include a written rotation plan, tillage systems that incorporate organic matter wastes into the topsoil, compliance with limits on the sources of manure and the timing of its application, prohibitions on the use of certain substances (e.g., sewage sludge, synthetic sources of nitrates, synthetic growth regulators, and anhydrous ammonia), a list of accepted and prohibited weed and pest control practices, segregation of organic and nonorganic production, record keeping regarding fertilization, cropping, and pest management histories, separate sales records for organic and nonorganic production, and records of all laboratory analyses.

The New Hampshire program requires growers to pay a \$100 annual inspection fee, and to provide a written description of their farm operation including the size of the farm, a field map, a three-year history of crop production, pest control, and fertilizer use, a crop rotation and a soil management plan, and a description of post-harvest storage and handling methods. Applicants for certification must also agree to comply with regulations controlling the use of the New Hampshire certified organic logo.

Organic Food Handling

In addition to growers, who actually produce and harvest products to be marketed as organic, there are handlers who transform and resell the organic products. Not all certifying agents have standards for handling organic products. Some have standards for parts of the food marketing system, such as retail food establishments, that are not explicitly covered by the OFPA or by the proposed regulation.

Definitions of processing and handling differ across certifying agents and State laws. Some States, such as Washington, distinguish between a processor and a handler, specifying 21 actions which constitute processing and defining a handler as anyone who sells, distributes, or packs organic products. Washington does not consider retail grocery stores and restaurants to be organic handlers or processors.

Marketing of Organic Food—Domestic and International

The marketing practices of organic producers range from roadside stands marketing directly to consumers, to marketing through wholesale markets, to direct marketing to restaurants and supermarkets. USDA does not have official national level statistics on organic retail sales. An industry trade publication reported estimates of retail sales of organic foods for a number of years in the 1990's (Table 1). The last published estimate was \$3.5 billion in 1996 (\$3.6 billion in 1998 dollars). To put this figure in context, total food expenditures by families and individuals were \$606 billion in 1996 (\$629 billion in 1998 dollars).

The United States is both an importer and an exporter of organic foods. The United States does not restrict imports of organic foods. In fact, U.S. Customs accounts do not distinguish between organic and conventional products. The largest markets for organic foods outside the United States are in Europe, Japan, and Canada. There is increasing pressure, particularly in Europe and Japan, for U.S. exports to demonstrate that they meet a national standard rather than a variety of private and State standards.

The EU is the largest market for organic food outside the United States. The organic food market in the EU was estimated to be worth \$5.2 billion in 1997 (International Trade Centre UNCTAD/WTO 1999). The largest organic retail sales markets in the EU in 1997 were Germany (\$1.8 billion), France (\$720 million), and Italy (\$750 million). Large organic markets outside the EU include Canada and Australia, with approximately \$60 million and \$68 million, respectively, in organic retail sales in 1997 (Lohr 1998). Import share of the organic food market in Europe ranged from 10 percent in France to 70 percent in the United Kingdom, was 80 percent in Canada, and varied from 0 to 13 percent in various Australian states.

Japan is another important market for U.S. organic products. Currently, Japan has voluntary labeling guidelines for 6 categories of non-conventional agricultural products: organic, transitional organic, no pesticide, reduced pesticide, no chemical fertilizer, and reduced chemical fertilizer. Total sales, including foods marketed as "no chemical," and "reduced chemical" are forecast to jump 15 percent in 1999 to almost \$3 billion. Imports of organic agricultural products were valued at \$90 million in 1998. Given Japan's limited agricultural acreage, imports will likely provide an increasingly significant share of Japan's organic food supply (USDA FAS 1999a).

Recently, these markets have adopted or are considering to adopt procedures that may impede the importing of organic food. The EU regulations establishing the basis for equivalency in organic production among EU members and for imports from outside the EU were adopted in 1991 (Council Regulation 2092/91). The EU regulations only allow imports from non-EU countries whose national standards have been recognized as equivalent to the EU standards (Commission Regulation 94/92).

The Ministry of Agriculture, Forestry, and Fisheries (MAFF) in Japan recently

announced proposed standards and third-party certification requirements. Under Japan's proposed standards, certifying agents from countries without national organic standards administered by a federal government will have to be accredited (registered) with MAFF to obtain approval to certify products destined for the Japanese market. The Japanese proposal includes provisions for country-to-country equivalency recognition of other national programs.

The Proposed Rule

The proposed rule follows the structure established in the OFPA. By adopting this alternative, the Department would follow legislative direction in the OFPA. All products marketed as organic will have to be produced and handled as provided in the OFPA and the regulations. Compared to current organic practices, the proposed rule sets a more stringent system of requirements.

Accreditation and Certification

The rule specifies the accreditation and certification process. Persons providing certification of organic production and handling must be accredited by USDA through the NOP. Applicants for accreditation must document their abilities to certify according to the national standards and to oversee their clients' compliance with the requirements of the OFPA and NOP regulations. Producers and handlers of organic products must be certified by an accredited certifying agent. Producers and handlers are required to document their organic plans and procedures to ensure compliance with the OFPA.

All certifying agents would have to be accredited, and certification by producers and handlers would not be voluntary. The exceptions are: (1) Growers and handlers with gross organic sales of \$5,000 or less would be exempt from certification; and (2) a handling operation may be exempt or excluded from certification according to provisions described in the rule's subpart B, Applicability. For example, a handling operation that is a retail food establishment or portion of a retail food establishment would be exempt if it handles organically produced agricultural products but does not process them, and would be excluded from the requirement to be certified if it processes or prepares, on the premises of the retail food establishment, raw and ready-to-eat-food from agricultural products that are previously labeled as "100 percent organic," "organic," or "made with organic (specified ingredients)." However, this exemption does not extend to other provisions of the proposed rule such as prevention of contact with prohibited substances.

USDA will charge applicants for accreditation a \$500 fee at the time of application. USDA will also charge applicants for costs over \$500 for site evaluation of the applicant's business. The applicant would be charged for travel costs, per diem expenses, and any miscellaneous costs incurred with a site evaluation. Review of documents for renewal of accreditation will be charged at an hourly rate.

Producers and handlers will not pay certification fees to USDA. Certification fees

will be established by the accredited certifying agents. USDA will not set fees. The rule requires certifying agents to submit a copy of their fee schedules to USDA, post their fees, and provide applicants estimates of the costs for initial certification and for renewal of certification.

Production and Handling

The rule establishes standards for organic production of crops and livestock and handling of organic products. These standards were developed from specific requirements in the OFPA, recommendations from the National Organic Standards Board (NOSB), review of existing organic industry practices and standards, public comments received on the 1997 proposal and subsequent issue papers, and public meetings.

The proposed rule establishes a number of requirements for producers and handlers of organic food. These requirements will affect farming operations, packaging operations, processing operations and retailers. Some of the major provisions are: (1) Land requirements; (2) crop nutrient requirements; (3) crop rotation requirements; (4) pest management requirements; (5) livestock management requirements; (6) processing and handling requirements; and (7) commingling requirements.

National List

The National List lists allowed synthetic substances and prohibited non-synthetic substances that may or may not be used in organic production and handling operations. The list identifies those synthetic substances, which would otherwise be prohibited, that may be used in organic production based on the recommendations of the NOSB. Only those substances on the National List may be used. The National List also identifies those natural substances that may not be used in organic production, as determined by the Secretary based on the NOSB recommendations.

Testing

When certifying agents have reason to believe organic products contain a prohibited substance, they may conduct residue tests. The rule incorporates the national mean of detected residues for specific commodity/pesticide pairs and clarifies how unavoidable residual environmental contamination would be used in residue testing.

Labeling

The rule also states how organic products may be labeled and permitted uses of the USDA organic seal. In addition to the USDA seal and the certifying agent's seal, information on organic food content may be displayed. It is important to note that small businesses who are certified may use the USDA seal.

Recordkeeping

The rule will require certifying agents, producers, and handlers to keep certain records. Certifying agents will be required to file periodic reports with USDA. Producers and handlers will be required to notify and submit reports to their certifying agent. While recordkeeping is a standard practice in

conventional and organic farming, the proposal adds recordkeeping and reporting requirements which do not exist for growers and handlers operating without certification. Similarly, certifying agents would face additional recordkeeping and reporting requirements, particularly those certifying agents operating without external accreditation. State and private certifying agents regulate the use of organic seals and logos. The proposed rule permits certifying agent logos and requires the name of the certifying agent on processed organic foods.

Alternatives to the Proposed Rule

As required by E.O. 12866, alternatives to the proposed rule were considered. The identified alternatives were the Status Quo and Industry-Developed Standards. The costs and benefits of each alternative were assessed to the extent possible.

Status Quo: The Organic Market in the Absence of Federal Regulation

This is the no program alternative. There would be no national standard or national program of accreditation and certification. Certification would be voluntary and certifying agents would not have third party accreditation. Some producers and handlers would operate with certification provided by private organizations or State programs. Other producers and handlers would characterize their foods as organic but would not be certified.

A mix of State and private programs may continue to operate according to varying standards. In States without organic laws or States where certification is voluntary, goods would be marketed as organic without third party certification. Even under this scenario, organic food produced in States with production standards and certification may be produced using similar practices because most State standards follow similar requirements: A 3 year transition, prohibited use of certain substances (lists of substances tend to overlap), practices which prevent commingling with conventional products, and where livestock standards exist, organic feed.

In addition, at the time the OFPA was enacted, the industry had been unable to agree on organic standards. Recently, there has been movement toward shared standards partly in response to efforts to develop national organic standards including the 1997 proposal and the public NOSB process. The Organic Trade Association (OTA) has developed "American Organic Standards" which the OTA Board recently ratified. The OTA describes itself as " * * * a national association representing the organic industry in Canada, the United States and Mexico. Members include growers, shippers, processors, certifying agents, farmer associations, brokers, consultants, distributors and retailers. Established in 1985 as the Organic Foods Production Association of North America, the Organic Trade Association works to promote organic products in the marketplace and to protect the integrity of organic standards." (OTA website). Although there is substantial consensus on the draft standards, acceptance is not unanimous.

The draft standards developed through OTA correspond closely to many elements in the proposed national organic program. OTA envisions a system of accreditation and certification of producers and handlers but not restaurants and grocery stores. The list of allowed and prohibited substances mirrors the list developed by the NOSB. Production practices for crops and livestock include the common features in most State and private programs—a 3 year transition, no commingling, use of organic feed, limits on the use of antibiotics, requirements for an organic plan and recordkeeping. Hence, even in the absence of a national program, the organic industry may be moving toward a common standard.

Under the status quo-no national program alternative, producers and handlers who chose to be certified, or who are required by State laws to be certified, would pay fees that would vary depending on the market for the particular private certifying agent's service and whether a State certification program was operating with subsidized fees.

No federal funds would be used, there would be no transfer from federal taxpayers at large to organic market participants, and there would be no federal regulatory barriers to entry into organic production and handling.

International access for domestic organic products may be very influential on development of the organic industry in the United States. A food trade publication (The Natural Foods Merchandiser) tracked organic sales for a while in the 1990s showing annual growth in retail sales of 20–25 percent between 1990 and 1996 (Table 1). This growth took place in the absence of a national program.

In the absence of national standards, U.S. organic producers have been able to access European markets only by obtaining specific product permissions granted to individual importers by organic regulatory authorities in an EU member state (Byng, p. 27–28 1994). This process has required the importer to satisfy the authorities, through documentation and possible site inspection, that the product in question has been certified to and produced under equivalent standards of production and inspection. This case-by-case process of approving imports was intended as a temporary arrangement to accommodate non-EU countries that had not yet established government systems regulating organic production and certification. Another step State and private organic certifying agencies have taken to access international markets in the absence of a national program has been a voluntary, fee-for-service program to verify that they comply with the requirements prescribed under ISO Guide 65.

Governments in foreign markets and foreign private processors and retailers are expected to insist on additional verification that goods have been produced to acceptable organic standards. This would likely lead to an increased use of private accreditation services and of USDA's ISO Guide 65 verification service. USDA's ISO Guide 65 verification services are provided on a user fee basis with full cost recovery. These private accreditations and USDA's

verifications would increase costs for certifying agents and producers and handlers. In addition, establishing reciprocity between certifying agents in the domestic organic market involves some cost and may stifle growth in trade of organic products, although the magnitude of these costs and their effects on growth is unknown.

Under the proposed national program, all applicants for accreditation will be assessed against ISO Guide 65, eliminating the need for a separate ISO Guide 65 assessment that exists for those exporting to the EU in the absence of a national program. Growth in the trade of organic products, particularly exports, may be jeopardized by a status quo-no program alternative because there would be no national program upon which to establish equivalency.

Industry-Developed Standards

As an alternative to the proposed national program, another national program could adopt industry-developed standards. For example, USDA could adopt the standards recently developed by the Organic Trade Association or other consensus standards and enforce those standards. Certification to these standards could be performed as it is currently, by private certifiers or by state programs. There could be variation among certifiers' standards, but producers and certifiers would not be able to prohibit use of a product meeting the national standard from the production of other "organic" products.

There are various enforcement mechanisms that are available under this alternative. The USDA could choose to enforce the adopted standards. Enforcement could be left to other federal agencies or State governments. For example, the Federal Trade Commission could regulate truth in advertising with respect to organic food; the USDA Food Safety Inspection Service could regulate labeling of organic meat and poultry products.

Adopting the industry standard as the USDA standard, the USDA could provide an acceptable national standard that would be necessary in establishing equivalency to access international organic markets, and eliminate the problems associated with establishing reciprocity in the domestic organic market.

It is important to note that it may be difficult to develop consensus industry standards. For example, while standards recently proposed by OTA were developed with significant industry input they may not represent the kind of consensus that is the result of this proposed rule.

Number of Affected Parties and Projections

In assessing the impacts of the rule, we have attempted to determine the number of certifying agents, private and State, that are currently operating, and considered the factors likely to affect the number of certifying agents after the rule is implemented. We have attempted to determine the number of currently operating producers and handlers that would be affected. And, we have considered the factors which might affect the number of producers and handlers after the program has been implemented.

For the analysis, the USDA assumes the following:

1. Forty-nine domestic certifying agents and ten foreign certifying agents will be affected by the proposed regulation.
2. Approximately 12,200 certified and non-certified organic producers will be affected by the proposed regulation. With the assumed growth rate of 14% for certified organic producers and approximately 8% for non-certified organic producers, the number of organic producers will grow to 17,150 in 2002.
3. Approximately 1,250 processors and handlers of organic food will be affected by the proposed action. This number will grow to 2,150 by 2002.
4. The number of retailers affected by the proposed action is not quantified.

Certifying Entities

We place the number of certifying agents currently operating at 49, including 13 State programs. The number of certifying agents has remained fairly stable, between 40 and 50, for some years, with entries and exits tending to offset each other. For purposes of estimating the paperwork burden described elsewhere, we assume no growth in the number of domestic certifying agents but project 10 foreign certifying agents in the first 3 years of the program.

Organic Producers

It is more difficult to establish the number of organic producers. Organic farming was not distinguished from conventional agriculture in the 1997 Census of Agriculture. Among the sources which give insight into the number of producers, the Organic Farming Research Foundation (OFRF) has conducted nationwide surveys of certified organic producers from lists provided by cooperating certifying agents (OFRF 1999). OFRF sent its 1997 survey to 4,638 organic producers.

Because OFRF did not obtain lists from all certifying organizations or their chapters (55 out of a total of 64 identified entities provided lists), its list count of 4,638 producers is likely an underestimate of the number of certified organic farms. If the average producer-to-certifying agent ratio (55 certifying agents to 4,638 producers) holds for the 9 certifying organizations that did not provide the list (9 certifying agents out of a 64 certifying agents), then the number of producer grows to 5,397 producers.

The different estimates of the number of certifying agents should be noted. The USDA estimates 49 certifying agents; the OFRF estimates 64 certifying agents. The difference stems from the USDA's not counting different chapters of certifying organizations separately.

The California Department of Food and Agriculture's organic registration program suggests that, at least for California, most organic producers are not certified. For the 1994-95 reporting period, CDFA reported that 1,372 farms registered as organic producers but only 517 of these farms were certified (Klonsky and Tourte, 1998a). Thus, one approach to projecting national totals from OFRF survey lists of certified producers would be to apply the 1994-95 ratio between

producers registered and certified in California to the OFRF 1997 list count. This would suggest the number of non-certified producers to be 8,918, resulting in the total number of organic producers to be 14,315. However, it is important to note that California's structure of organic production may not be representative of the national profile. The number of non-certified producers may be higher or lower.

CDFA also reports the number of registered and certified producers by sales class. Many producers would likely be eligible for the small farm (sales less than \$5,000) exemption provided for in the OFPA. Of 1,372 registered organic farms in California, 907 had sales of less than \$10,000. Of the 517 certified farms, 188 had sales of under \$10,000. If these ratios are applied to the number of producers calculated, then the number of certified producers with sales under \$10,000 would be 1,962, and the number of organic producers in general with sales under \$10,000 would be 9,463. Thus, there are potentially a large number of farms which could be exempt from certification requirements.

Dunn (1995a, 1995b, and 1997) has estimated the number of certified organic producers in the United States. Dunn (1995a, 1995b) estimated the number of certified producers at 4,060 in 1994. Dunn (1997) reported 4,856 certified organic farms in 1995. USDA's 1997 proposal relied on Dunn's 1995 estimate of 4,060 total certified producers. Dunn's numbers have been used because Dunn's 1995 work was an official USDA study. The methods used were reviewed by USDA and the resulting estimates are official USDA statistics. Although Dunn's 1997 estimates were not a USDA study, the 1997 study used the same approach as the 1995 study.

An adjustment is needed to account for the number of producers who are practicing organic agriculture but who are uncertified and would be affected by this proposed rule. We reject the idea of expanding by the certified-to-registered ratio reported in California for reasons previously stated. We assume that the number of organic-but-not-certified producers in 1999 is about 4,000. We adopt this figure recognizing that there may be 1,000 such farms in California, given that there were 855 in CDFA's report on 1995 registrations. The total number of organic farms for assessing the impact of the rule is 12,200 in 1999.

Data collected by AMS indicate that the number of certified organic farmers increased about 12 percent per year during the period 1990 to 1994. OFRF survey efforts indicate that growth has continued, though it is not clear whether the growth rate has changed. We use the average growth rate from Dunn's time series from 1991-1994, which was about 14 percent. The true rate of growth could be higher or lower. By applying the 14-percent growth rate to Dunn's (1995) estimate, the number of certified organic producer potentially affected in 1999 is 8,200 and 12,150 in 2002.

We have no national-level growth rates for not-certified organic farms. The limited times series from CDFA is of limited value in estimating a growth rate. We suspect it is less than the rate for certified farms because

certification has value and organic producers would be expected to take advantage of the marketing advantages of certification. Furthermore, the emergence of State certification programs that appear to have lower certification fees than private certification entities may have encouraged more organic producers to be certified. Therefore, for purposes of analyzing the impacts of the rule for the Paperwork Reduction Act, we assume growth of non-certified organic producers from 4,000 in 1999 to 5,000 non-certified farms by 2002, making the total number of farms potentially affected by the rule, 17,150 farms. However, we request comment and/or data on the number and the growth of certified and non-certified organic farms.

Organic Handlers

Little information exists on the number of handlers. They include processors such as organic soup manufacturers, organic food packaging operations, and organic food wholesalers. USDA has estimated that there were 600 entities in this category in 1994 (Dunn 1995b). AMS estimated that the growth rate was 11 percent from 1990 through 1994 (Dunn 1995b). More recent data from CDFA registration records suggest a growth rate of about 28 percent (California Department of Health Services 1999). For projection purposes, we use a growth rate of 20 percent, which makes the number of handlers for 1999 1,250 and for 2002 2,150. Reasons for growth include the general increase in organic production and growth in the market for processed organic foods, including multiingredient products. Again, these projections are based on limited data from the early 1990's, and growth may have slowed or increased. We request comment and/or data on the number and the growth rate of processors and handlers in the organic industry.

Retail Food Establishments

Retailers of organic food are grocery stores, bakeries, restaurants and other establishments that process or prepare raw and ready-to-eat food. Most are not currently subject to either voluntary practices or mandatory standards of the organic industry. Although they are excluded from the certification requirements, they are subject to other processing, handling, and other production related requirements of the proposed rule. Hence, a new stratum of the organic industry will be regulated by the proposed rule.

Dunn's (1995a) estimates the number of certified retailers to be 31 in 1995. It is not clear whether Dunn's (1995a) definition of retailers and the proposed definition stated above are consistent. Hence, the total number of retailers that may be regulated remains unknown. USDA's Economic Research Service (ERS) reports there were 161,707 grocery stores in 1997 (ERS website). Many of these stores sell organic products and may be affected by the proposed rule. The effect of the proposed regulation on the growth of retailers remains unknown. We request comment and/or data on the number and the growth rate on the retailers of organic food.

Foreign Entities

The discussion of the number of affected parties has focused on domestic certifying agents, producers, and handlers. We recognize that foreign entities may apply for accreditation and foreign producers and handlers may be certified under the NOP. Furthermore, upon request of a foreign government, a foreign certifying agent may meet the requirements for accreditation when the Administrator determines that the certifying agent meets the requirements of the NOP.

At this time, we have no information regarding the number of foreign entities which may enter the NOP. We do not know how many foreign producers and handlers are marketing goods as organic, nor do we know how many will seek to be certified under the NOP. Accredited certifying agents will be able to certify operations outside the United States and foreign certifying agents may become accredited by USDA. It is likely that the costs for accreditation will be higher for foreign applicants for accreditation. Foreign applicants will face the same costs as domestic applicants but the levels of cost would reflect generally higher costs of foreign travel and per diem expenses for site evaluation and miscellaneous costs such as for translation of documents. For purposes of estimating the paperwork burden described elsewhere, we assume 10 foreign certifying agents in the first 3 years of the program. We request comment and/or data on the number and the growth rate of foreign entities that may export to the U.S. organic market.

Benefits of the Proposed Rule

The benefits from implementation of the proposed rule are: (1) Improved protection of buyers from misleading claims and more information on organic food; (2) reduced administrative costs; and (3) improved access to international organic markets. Not all benefits that may arise from the rule are quantifiable. Where economic data are available, they may relate to costs and are generally not adequate to quantify economic benefits.

Information

Potential benefits to consumers as a result of the proposed rule include more information on organic food, and protection from false and misleading organic food claims. Consumers may be misled by labels on processed and raw products claiming to be organic. In particular, with processed food, some of the ingredients may not be organically produced, or the product may contain less organic content than the consumer assumes. The USDA organic seal will provide consumers a quick tool to verify that goods offered for sale as organic are in fact organic. To the extent that consumers view the seal as an important information too, that is, product with the seal is perceived as more desirable, they may enhance the ability of producers to realize the price premiums associated with certified products.

There is anecdotal evidence to suggest that consumer fraud involving organic food does occur (Mergentime 1997). Criminal prosecutions involving felony pleas and fines have taken place (Mergentime 1997).

However, we have no evidence to suggest that this problem is wide-spread (Mergentime 1995). Also, it is important to recognize that the organic industry's effort to police itself and the remedies provided by the judicial system may be adequate to address consumer fraud. Mergentime (1997) documents the effect of litigating fraud cases on the industry. However, we request comment and/or data on the extent and the severity of consumer fraud that may exist.

Some producers may have limited their organic livestock production because of uncertainty regarding the standards that would be used in the NOP. By removing the uncertainty, producers may increase production, thereby increasing the quantity of livestock products.

Reduced Administrative Costs

The proposed rule addresses the problem of existing certifying agents using different standards and not granting reciprocity to other certifying agents. By accrediting certifying agents, the rule would establish the requirements and enforcement mechanisms that would reduce inconsistent certification services and lack of reciprocity between certifying agents. In the current system, the certifying agent of a final product is not required to recognize the certification of an intermediate product. Both primary farmers and food handlers may face a risk of being unable to sell a certified organic product when more than one certifying agent is involved. By imposing a uniform standard of certification and production, costs associated with establishing reciprocity between certifying agents will be eliminated. However, the magnitude of this benefit cannot be gauged without quantification. In particular, with the increasing consensus within the organic industry, the benefit may not be large.

It is important to distinguish between consensus with respect to standards of production and consensus with respect to certifying agents practices. There is growing consensus regarding crop standards, livestock standards are more problematic. And, consensus is least evolved regarding standards of conduct and practice for certifying agents. There is no consensus regarding whether certifying agents should be accredited or who the accrediting body should be.

Industry-wide training costs may decrease. The proposed uniform standards of production, certification should enable organic inspectors to move more easily from one certifying agent to another than the current system.

In addition, USDA accreditation of certifying agents would present opportunities for sharing information about standards, practices, and the general requirements of the program through the NOP staff. USDA will undertake a number of outreach and education efforts in connection with the launch of the NOP. Compliance guides and other printed material will be prepared which will be more readily understood than the **Federal Register** document. NOP staff will participate at industry meetings and will likely host public information exchange meetings.

International Markets

The final national program rule is expected to lead to EU acceptance of NOP certified organic products. That is, it is anticipated that the EU would determine that the NOP is acceptable vis-a-vis EU regulation 2092/91. Article 11 of EU Reg. 2092/91 establishes the conditions under which organic products may be imported from third countries and addresses the framework for equivalency. The NOP is a national program that should be acceptable to the EU and other governments. The result would be the removal of trade restrictions, thereby possibly increasing the growth in exports of organic food products.

Currently, despite restricted access to the European market, the United States is the most important non-EU supplier of organic products to EU countries (Foreign Agriculture Service (FAS), 1995). Import authorizations have been granted for a number of raw and processed commodities, including sunflowers, buckwheat, beans, sugar, and apples. Demand is strong throughout the European market, and the organic market share was 1–2 percent of total food sales in 1997 (Collins).

Lohr (1998) cites several growth projections:

Annual growth rates of 25% to 30% have been experienced in the EU, the United States, and Japan for over five years, but growth is already slowing in some product categories (PSC, Scott) * * * Segger projects that the EU market will reach \$58 billion and the U.S. market \$47 billion by 2006. Ahmed suggests that the Australian market could grow to \$571 million by 2000, whereas LaFond projects that the value of Canadian organics will reach \$145 million by 2006. Mergentime forecasts the Japanese market will reach \$2.6 billion by 2000 (Lohr, 1126).

Lohr further states that these projected future growth rates are based on straight-line extrapolations of current sales and growth rates without understanding the underlying market mechanisms and price elasticities (Lohr 1998).

Foreign acceptance of the U.S. national standard can be expected to expand the universe of consumers for U.S. producers and reduce costs of negotiating and documenting shipment by shipment.

Costs of the Proposed Rule

The costs of the proposed regulation are the direct costs of complying with the specific standards. It is important to note that while some costs associated with accreditation and certification are quantified, costs stemming from other provisions of the proposed regulations are not. In addition, this is a short-run analysis. The analysis examines the costs that may be incurred from 1999 to 2002. It is not possible at this time to conduct a longer-run analysis because we do not know enough about the fundamental supply and demand relationships to make economically sound long run projections.

Accreditation Costs

USDA has identified 36 private certifying agents and 13 State programs providing certification. These 49 entities are considered likely applicants during the first 18 months

during which USDA will not charge application fees or hourly fees for accreditation. An unknown number of new entrants to the certifying business may also apply. However, over the last 10 years, the number of certifying agents does not appear to have grown significantly, with the net effect of entries and exits maintaining a population of certifying agents at about 40–50.

The proposed rule would allow USDA to collect fees from certifying agents for USDA accreditation. Collecting fees from certifying agents only is administratively simpler and will enable State programs that want to keep client costs low to do so.

Applicants for accreditation will be required to submit a nonrefundable fee of \$500 at the time of application, which is applied to the applicant's fees for service account. This means that the \$500 fee paid at the time of application is credited against any subsequent costs of accreditation arising from the site evaluation. The \$500 fee is the direct cost to applicants who are denied accreditation based on the initial review of the information submitted with their application. Charges for the site evaluation visit will cover travel costs from the USDA employees' duty station, per diem expenses for USDA employees performing the site evaluation, an hourly charge that we anticipate will not exceed \$95 per hour (per each employee) for services during normal working hours (higher hourly rates will be charged for overtime and for work on holidays), and other costs associated with providing service to the applicant or certifying agent.

The anticipated hourly rate is the rate that USDA will charge for services under the Quality Systems Certification Program (QSCP). A separate rulemaking will establish the precise hourly rate that will be charged. Our preliminary estimate that the fee will be no more than \$95 per hour is presented to give the public some indication of the rate that will be charged following the 18-month transition period. QSCP is an audit-based program administered by AMS, which provides meat packers, processors, producers, and other businesses in the livestock and meat trade with the opportunity to have special processes or documented quality management systems verified. The procedures for accreditation evaluation are similar to those used to certify other types of product or system certification programs under QSCP.

At present, the base per diem for places in the United States is \$80 (\$50 for lodging and \$30 for meals and incidental expenses). Per diem rates are higher than \$80 in most large cities and urbanized places. Travel costs will depend on where the certifying agent is located.

USDA estimates the costs of a site evaluation visit after the transition period will average \$3,070–\$4,850 depending on the characteristics of the applicant. This estimate is based on experience with the QSCP and more limited experience performing audits verifying that certifying agents meet ISO Guide 65. The cost of a site evaluation visit will vary with the cost of travel from the USDA reviewer's duty station to the

applicant's place of business. In general, more distant and more remote locations will involve higher travel costs.

Accreditation will include verification of adherence to ISO Guide 65. Recent experience with USDA's program to verify organic certifying agents to ISO Guide 65 indicates that roughly 32 staff hours are required. Although much of the accreditation site evaluation will involve comparisons against ISO Guide 65, additional hours will be required because USDA will be evaluating additional aspects of the applicant's operation to determine if the applicant is qualified to perform as an accredited agent for the NOP. Based on experience with ISO Guide 65 verifications, we project that small applicants with a simple business structure will require 3 days and large applicants with more complex business structure will require 5 days. Thus, the total number of hours to be charged would range from 24 to 40 hours. At the base rate of \$95.00, the charge for hours of service would be \$2,280–\$3,800.

Per diem costs would cover 3 to 5 days, totaling \$240–\$400. A review of domestic travel by USDA staff during fiscal year 1999, indicates that transportation costs ranging from \$500–\$600. Miscellaneous costs are estimated to add another \$50 to each site visit. Thus, the total site visit cost would range from \$3,070 to \$4,850.

During the 18-month transition period, USDA intends to use 2 reviewers for site evaluation visits. One reviewer will come from the QSCP audit staff and will be familiar with the ISO Guide 65 verification; the other reviewer will come from the NOP staff and will be familiar with requirements of the organic program. The two will conduct the site evaluation jointly. We anticipate only one reviewer will be required after the transition period. During the 18 month transition period, applicants will be charged for travel and per diem costs for two persons, but not application fees or hourly fees. Thus, the estimated expenditures (travel and per diem) for these initial accreditations will be \$1,530–\$2,050. Table 3 estimates the total initial costs for an applicant to become accredited.

Currently few private certifying agents are operating with third party accreditation. Fetter (1999) reports that in a sample of 18 certification programs four programs were accredited and one had accreditation pending. All of these were large, private certifying agents. Those certifying agents currently accredited by third parties will likely pay less for USDA accreditation. In its first proposal, USDA stated at FR 62:65860, "We are aware that certifiers currently may pay in excess of \$15,000 for accreditation by a private organization." Commenters thought this figure was too high. One commenter, which operates the International Federation of Organic Agriculture Movements (IFOAM) Accreditation Programme under license to IFOAM, stated "It is possible that the largest programme operating a chapter system with activities in many countries (which is included in their IFOAM evaluation) paid this amount in their first year. On the other hand the average cost to a medium sized certifier works out at around \$3000 to \$4000 per year." Another commenter stated "At the

present time IFOAM accreditation costs less than \$10,000/year for the largest certifier and \$3–5,000 for smaller certifiers."

The direct costs of accreditation, if all currently operating certifying agents become accredited during the first 18 months following the final rule, is approximately \$75,000 to \$100,000. This figure is derived from the per firm costs in Table 3. After the first 18 months, the direct cost for accrediting 49 certifying agents would be approximately \$150,000 to \$238,000.

The 18 month period affects the distribution of program costs between the organic industry and the taxpayer. Some of the costs of accreditation would be absorbed by the NOP operation budget appropriated by Congress. In effect, the taxpayers are subsidizing the organic industry. Without this subsidy, the total cost of accreditation may approach \$1 million.

Private certifying agents and state programs that do not mirror the proposed regulation may incur additional costs to change their programs to adopt the proposed national standards. The discussion on the effect of the proposed regulation on existing state programs is in "State Program Costs." The cost associated with changing existing private certifying programs is not quantified.

Also, certifying agents who have been operating without third party accreditation will face new costs. Compared to the direct costs of \$3,000–\$5,000 per year indicated by the commenters, the direct costs of USDA accreditation will be smaller. The direct costs for certifying agents obtaining accreditation during the first 18 months, when USDA will not impose an application fee or hourly charges, will be limited to travel and per diem costs. Furthermore, USDA's charges are imposed every 5 years, not annually.

A national accreditation program may shrink the market for a third-party accreditation. Certifying agents will have little incentive to maintain or seek a second accreditation by a private organization unless that accreditation sufficiently enhances the market value of the certifying agent's services. Thus, the market will determine whether other accrediting entities continue to have a U.S. market for their services.

Training programs are currently offered by the Independent Organic Inspectors Association (IOIA), an organization of approximately 165 organic certification inspectors, and by some of the larger certifying agents (IOIA, p. 1). Costs to existing certifying agents to provide additional training to other staff are difficult to measure in the absence of information on current staff skill levels or the existence of formal training other than inspector training. Some agencies rely on volunteer staff who may have had no formal training, but the extent of this practice is unknown. AMS intends to offer assistance to certifying agents, producers, and handlers by providing guide books and other printed material that would enable participants to better understand the regulations. In addition, AMS intends to continue open and frequent communication with certifying agents and inspectors to provide as much information as possible to aid them in fulfilling the requirements of the regulations.

The OFPA requires that private certifying agents furnish reasonable security, such as a bond, for the purpose of protecting the rights of participants in the organic certification program. Specific requirements regarding reasonable security have not yet been established. It is expected that there will be costs to certifying agents from these requirements.

Certification Costs

State laws vary widely on organic certification and registration. Some States require only that an organic producer register and make certification voluntary. Other States require certification by the State's own agents, while others accept certification by a private certifying agent. The least stringent requirement among States with organic legislation is that products marketed as organic comply with their definition of organic but both registration and certification are voluntary. Thirteen States operate programs to certify organic production. In many States producers may claim their product is organic but operate without certification or well-defined standards. On the other hand, many organic producers operate in States with no program and voluntarily secure third party certification to well-defined standards.

Under the proposed rule, USDA will not impose any direct fees on producers and handlers. Certifying agents will establish a fee schedule for their certification services that will be filed with the Secretary. Certifying agents will provide all persons inquiring about the application process with a copy of their fees. The certifying agent will provide each applicant with an estimate of the total cost of certification and an estimate of the annual costs of updating the certification. However, the certifying agent may require applicants to pay at the time of application a nonrefundable fee of no more than \$250 which must be applied to the applicants' fee-for-services account. The \$250 limit is proposed as a reasonable figure considering the interests of certifying agents and applicants.

The proposed maximum nonrefundable fee protects certifying agents by ensuring that they receive some payment for their work for applicants should the applicant lose interest or be found unqualified for certification. For the purposes of estimating the cost of the paperwork burden on certifying agents, USDA has valued their time at \$27 per hour. Thus, the \$250 limit, if the certifying agent chooses to require it, would cover approximately 9 hours of work. The \$250 limit protects applicants from paying large fees up front when their ultimate eligibility for certification is unknown. The \$250 limit is believed to be low enough to ensure producers and handlers can afford to take the first steps for certification but high enough to ensure certifying agents will have an incentive to initiate certification when the prospects that the applicant will qualify are unknown.

Some States charge minimal fees for certification by subsidizing operating costs from general revenues. The majority of certifying agents structure their fee schedules on a sliding scale based on a measure of size,

usually represented by the client's gross sales of organic products but sometimes based on the acres operated (Fetter 1999 and Graf and Lohr 1999). Some certifying agents charge an hourly rate for inspection and audit services.

Graf and Lohr have applied fee schedules provided by nine certifying agents to four hypothetical farms—small, medium, large, and a super farm. Tables 2A and 2B summarizes the fees that Graf and Lohr found by applying schedules of each certifying agent to hypothetical farms. Total first-year costs and subsequent (renewal) year costs for certification are shown. The average cost for each size class should be interpreted with care because the reported average is not weighted by the number of clients certified. In their study, the Texas Department of Agriculture program is the low-cost certifying agent for all-size operations. The high-cost certifying agent differs across farm sizes. None of these certification programs mentions costs for residue testing, which the NOP will require in the form of preharvest testing when there is reason to believe that agricultural products have come in contact with prohibited substances. Preharvest testing is expected to be infrequent. Some certifying agents currently require soil nutrient testing and water quality testing. The estimated total initial costs for a producer or handler to become certified are presented in Table 3.

We have not extended the average costs reported in Tables 2A and 2B to aggregate certification costs for all organic farms because the number of organic farms is not known with precision, nor is their geographic location and there are no data to distribute the population of organic farms across size classes. Like conventional agriculture, the largest percentage of farms would be expected to fall in the smallest sales class. Many of the smallest farms would qualify for the small farm exemption from certification.

In addition, organic producers and handlers would incur the costs associated with becoming familiar with the national program. We request comment and/or data on the certification costs that may be imposed on the organic producers, handlers, processors, and retailers.

Production and Handling Costs

Producers and handlers currently active in the organic industry may bear costs under the proposed national standards. We believe that while some provisions of the proposed program mirror current industry practices, others differ. In addition to the cost associated with becoming familiar with the national program, any adjustments stemming from these differences will result in costs. These costs are only qualitatively discussed. This assessment does not include a provision-by-provision analysis of possible alternatives.

Producers

Producers of organic food will face numerous provisions that will regulate their production methods. As indicated in the Baseline section, many of the requirements are currently practiced by certified organic farmers. Farming operations that are not certified, but are registered with a State

government such as California, receive copies of the State laws to which they must comply. Some organic producers are neither certified nor registered and therefore may not practice the requirements proposed. Major provisions are discussed to illustrate costs; other provisions may also impose additional costs. We request comment and/or data on the costs that may be imposed on the producers of organic products. In addition, we request comment and/or data on the similarities and differences between the current practices of private and State programs and the proposed requirements.

Land Requirement. The transition period, which would specify the time during which prohibited materials cannot be applied before a field can be certified as organic, is included in many private and State organic standards. The OFPA specifies a required transition period of 3 years before certifying a field. The effect of this provision on the currently certified organic farming operations may be minimal. Certifying agents currently enforce the 3 year transition period required by the OFPA. Producers who are registered in States requiring registration, receive copies of the State laws governing organic production which generally require a 3 year transition period.

The effect on small farming operations that are neither certified or registered may be significant. Small farming operations that have completed a 3 year transition period and can document the transition will not be affected by this requirement. To stay in the organic industry, those who have not completed the 3 year transition period must comply with the transition period requirement. They may incur the cost of organic production for a significant length of time, yet not be allowed to sell their products as organic. Hence, some small organic operations may exit the industry. We request comment and/or data on the magnitude of the cost associated with the provision. In addition, we request comment and/or data on the similarities and differences between the current practices of private and state programs and the proposed requirements.

Soil fertility and crop nutrients. Lacking information, we have not quantified the cost associated with this provision, but we assume that it may have costs. Organic production historically rests on soil fertility management. Private and State certifying agents have well developed standards addressing care and treatment of the soil. The proposed rule includes requirements for the use of manure and a practice standard for composting which may impose additional costs to producers. However, not all organic farmers use manure for soil fertility and many farmers use composting practices that are consistent with the proposed rule. We believe that this requirement will have minimal impact on certified or registered organic producers. We request comment and/or data on the magnitude of the cost associated with the provision. In addition, we request comment and/or data on the similarities and differences between the current practices of private and State programs and the proposed requirements.

Materials list. Lists of approved synthetic materials, including soil amendments and

pesticides, vary from one State program to another. A detailed analysis of specific differences in the various existing materials lists shows them to be overlapping in most cases. The impact of the national program will be determined by how the national standards differ from current certification standards and from actual practice.

Farming operations, both certified and registered, may need to adjust their production methods to comply with the list. These adjustments will impose costs on these operations. However, most currently certified operations and those operating under a State program already adhere to a materials list. These lists overlap in most cases with each other and the National List in this proposal which should mitigate the costs for these operations. The magnitude of the costs resulting from these adjustments is not quantified. We request comment and/or data on the magnitude of the costs associated with the provision. In addition, we request comment and/or data on the similarities and differences between the current practices of private and state programs and the proposed requirements.

Animal drug use. Another common feature of organic standards is the restricted use of animal drugs for livestock. Where livestock standards have been adopted by existing State programs and by private certifying agents, most prohibit the use of animal drugs except for the treatment of a specific disease condition, and use of animal drugs is generally prohibited within 90 days prior to the sale of milk or eggs as organic. Some State and private certifiers allow the use of animal drugs in animals for slaughter if the producer extends the withholding period. Others prohibit the use of animal drugs. The standards in the proposed rule would prohibit the sale as organic of an edible products derived from an animal treated with antibiotics or other unapproved substances.

The proposed standards may not differ from existing State or private standards in prohibiting the use of drugs on healthy animals. However, the effect of this provision may differ among certified and registered organic farms. The effect on the certified farming operations is unknown. We assume that this provision may have costs, but the magnitude of these costs is not quantified. We request comment and/or data on the magnitude of the costs associated with the provision. In addition, we request comment and/or data on the similarities and differences between the current practices of private and state programs and the proposed requirements.

Other livestock requirements. Lacking information, we have not quantified the cost associated with this provision, but we assume that this provision may have costs due to the variability in current housing, feed and health care practices. We request comment and/or data on the magnitude of the costs associated with the provision. In addition, we request comment and/or data on the similarities and differences between the current practices of private and state programs and the proposed requirements.

Residue Testing. Lacking information, we have not quantified the cost associated with this provision, but we assume that this

provision may have costs. We request comment and/or data on the magnitude of the costs associated with the provision. In addition, we request comment and/or data on the similarities and differences between the current practices of private and state programs and the proposed requirements.

Handling requirements. These requirements prohibit a handler from using ionizing radiation for any purpose, an ingredient produced with excluded methods, or a volatile synthetic solvent in or on a processed agricultural product intended to be sold, labeled, or represented as "100 percent organic", "organic" or "made with organic (specified ingredients)." We believe, however, that the additional costs associated with compliance may be small. We base this assumption on the thousands of comments on the first proposal, including comments from the organic industry, indicating that these practices are widely considered to be inconsistent with organic production and handling. Lacking information, we have not quantified the cost associated with this provision. We request comment and/or data on the magnitude of the costs associated with the provision. In addition, we request comment and/or data on the similarities and differences between the current practices of private and state programs and the proposed requirements.

Handlers

Handlers of organic food may be defined and regulated differently across different certifying agents and States. Handlers may incur some cost associated with complying with the requirements of the proposed regulation. We request comment and/or data on the costs that may be imposed on the retailers of organic products. In particular, we request comment and/or data on costs associated with excluded methods, residue testing, and labeling. In addition, we request comment and/or data on the similarities and differences between the current practices of private and state programs and the proposed requirements.

Retail Food Establishments

Largely, retailers of organic food are not regulated. However, they are still subject to other requirements such as prevention of contamination of organic products with prohibited substances, and commingling organic with non organic products. Complying with these provisions may incur some cost. We request comment and/or data on the costs that may be imposed on the retailers of organic products.

Labeling Costs

Certified handlers will have to comply with requirements regarding the approved use of labels. The estimated annual cost for 1,977 certified handlers to determine the composition of 20 products to be reported on labels is \$948,960. This figure is based on an average of 1 hour per product and an hourly cost of \$27. Similarly, certified handlers will have to design their labels to comply with the regulation. This is expected to take 1 hour per label at \$27 per hour for a compliance cost of \$948,960. Total label costs for certified handlers are \$1.9 million.

Any producers, processors, and retailers who are not currently certified but who package organic products are also subject to the labeling requirements. Any changes to existing labels and new labels that need to conform to the proposed regulation will incur a cost. The costs associated with these activities are not quantified. Hence, the lower bound on the labeling cost is approximately \$2 million. We request comment and/or data on the extent the current labels will need to change to conform to the proposed regulation. In addition, we request comment and/or data on the similarities and differences between the current practices of private and state programs and the proposed requirements.

State Program Costs

A national program may impose additional costs on States by requiring changes in their existing programs. The proposed rule encompasses most of the principles of existing State programs. However, there are also departures.

Where State standards are below Federal standards or where elements of the Federal standards are missing from a State program, these States would be required to make changes in their programs that they might otherwise not make. Where State programs have standards in addition to the Federal standards and they are not approved by the Secretary, States also would be required to make changes in their programs. States without organic standards or whose current standards either would conform to those of the national program or would be approved by the Secretary would not incur additional costs resulting from required changes. Currently, USDA cannot predict which States may be required to adjust their existing programs.

States will be charged for accreditation, something none of them pay for now. The cost associated with this provision is discussed in the Accreditation Section.

Enforcement Costs

Enforcement costs will fall upon USDA's NOP, States operating State programs, and on certifying agents. Certifying agents will review clients' operations and will notify clients of deficiencies. Certifying agents can initiate suspension or revocation of certification. Certifying agents will be aware of these overhead costs and we assume that they will establish fee schedules that will cover these costs. Actual costs to certifying agents for enforcement activities will depend on the number of clients, how well informed clients are of their obligations, and client conduct. State programs will face the same obligations and types of costs as private certifying agents.

USDA's enforcement costs are costs associated with ensuring private certifying agents and State programs fulfill their obligations. USDA will bear costs of investigating complaints, monitoring use of the USDA organic seal and organic labeling, and taking corrective action when needed. USDA will bear costs related to reviewing an applicant's or certified operation's appeal and for administrative proceedings. We request comment on the costs of the

enforcement provisions of the proposed regulation.

Reporting and Recordkeeping Costs

The Paperwork Reduction Act of 1995 requires an estimate of the annual reporting and recordkeeping burden of the proposed NOP. Detailed descriptions of individual elements of that burden are presented in the proposal under the heading Paperwork Reduction Act of 1995. The estimated annual reporting and recordkeeping burden reported is approximately \$6.8 million. This figure should be understood within the context of the requirements of the Paperwork Reduction Act. The Paperwork Reduction Act requires the estimation of the amount of time necessary for participants to comply with the proposed regulation in addition to the burden they currently have. Information gathered by AMS in auditing activities in conjunction with ISO Guide 65 verifications, leads us to believe that the paperwork burden on current certifying agents and certified operators will be 10 to 15 percent greater than their current business practices as a result of this proposal.

Certifying Agents. The regulation will impose administrative costs on certifying agents for reporting and recordkeeping. The actual amount of the additional administrative costs that would be imposed by the proposed rule is expected to be different for those entities which would begin their activities only after the national program is implemented. Certifying agents that currently are active in the organic industry already perform most of these administrative functions; therefore, the additional costs to them would depend upon the extent to which their current practices are different from the requirements of the proposed regulation. An estimate of the cost of compliance is the annual reporting and recordkeeping burden documented in the Paperwork Reduction Act of 1995 analysis. Table 4 shows the estimated annual costs for State certifying agents and for private or foreign certifying agents. Based on the projected number of States agents (13) and private or foreign agents (46) the total reporting and recordkeeping cost, which captures much of the compliance costs of the rule, is \$1,113,192.

The following list describes several of the most significant proposed administrative requirements or optional submissions and the probable resources required for compliance. Details on the reporting and recordkeeping burdens estimated for each item are in the paperwork analysis.

1. A list of farmers, wild crop harvesters and handlers currently certified. This information can be compiled from existing records. After implementation, certifying agents will be required to submit on a quarterly basis a list of operations certified during that quarter.

2. A copy of procedures used for certification decisions, complying with recordkeeping requirements, maintaining confidentiality of clients' business-related information, preventing conflicts of interest, sampling and residue testing, training and supervising personnel, and public disclosure of prescribed information concerning

operations they have certified and laboratory analyses. These policies may have to be created or modified to conform to the regulation.

3. Documentation on the qualifications of all personnel used in the certification operation, annual performance appraisals for each inspector and personnel involved in the certification, and an annual internal program evaluation. Existing certifying agents may already perform these operations. New certifying agents will have to establish procedures to achieve these things.

4. Documentation on the financial capacity and compliance with other administrative requirements (e.g., fee structure, reasonable security to protect the rights of the certifying agents' clients as provided in the NOP, and business relationships showing absence of conflicts of interest). Some of this information can be compiled from existing records, e.g., fee schedules, and some may be generated from other sources.

5. Copies, submitted to USDA, of notices issued involving denials of certification, noncompliance, and suspension or revocation of certification. This requirement will be fulfilled simultaneously with sending notices to applicants or clients.

6. An annual report to the Administrator including an update of previously submitted business information, information supporting any requested changes in the areas of accreditation, and steps taken to respond to previously identified concerns of the Administrator regarding the certifying agent's suitability for continued accreditation. The annual report requirement will draw on records created in the normal course of business.

7. Retention of records created by the certifying agent regarding applicants and certified operations for not less than 10 years, retention of records obtained from applicants and certified operations for not less than 5 years, and retention of other records created or received for USDA accreditation for not less than 5 years. This activity requires records and database management capabilities and resources (storage space, file cabinets, electronic storage, etc.). In an informal inquiry, AMS found that most existing certifying agents currently retain records for at least 10 years and use both electronic and paper storage. We believe that this requirement will not pose an additional burden on existing certifying agents.

8. Public access to certification records, such as a list of certified farmers and handlers, their dates of certification, products produced, and the results of pesticide residue tests. This requirement will have minimal impact given the requirements for retaining records.

9. Providing program information to certification applicants. To comply with this requirement, certifying agents may need to modify existing standards and practices. The criteria for qualified personnel in the proposed rule may likely result in an increase in labor costs for some existing certifying agents and, initially, an increase in training costs. The amount of additional costs to these certifying agents would depend on the level of expertise among current certification agency staff, the extent to which

certifying agents currently rely on volunteers, and the current costs of training certification staff.

Producers and Handlers. The regulation will impose administrative costs on producers and handlers for reporting and recordkeeping. The actual amount of the additional administrative costs that would be imposed by the final rule is expected to be different for those entities that would begin their activities only after the national program is implemented. Producers and handlers who currently are active in the organic industry already perform most of these administrative functions; therefore, the additional costs to them would depend upon the extent to which their current practices are different from the requirements of the final regulation. An estimate of the cost of compliance is the annual reporting and recordkeeping burden documented in the Paperwork Reduction Act of 1995 analysis.

The following list describes several proposed administrative requirements or optional submissions and the probable resources required for compliance.

1. Establish, implement, and update annually an organic production or handling plan. Organic plans are a standard feature in the organic industry and are required by certifying agents. Thus, producers and handlers who are already involved in organics, can rely on their current plan with revisions as needed to meet elements of the national program which are new to them or differ from their current practice. Although producers and handlers are generally aware of the goals of organic plans, current practice may fall short of the rigor that will be required by the national program. New producers and handlers will have higher costs because they will have to prepare a plan from scratch.

2. Maintain records pertaining to their organic operation for at least 5 years and allow authorized representatives of the Secretary, the applicable State program's governing State official, and the certifying agent access to records. Existing organic producers and handlers maintain records. New producers and handlers will have to develop records systems. Access is expected to be infrequent, will require little time of the certified entity, and will not require buildings or equipment other than what is required for storing records.

3. Notify the certifying agent as required, e.g., when drift of a prohibited substance may have occurred, and complete a statement of compliance with the provisions of the NOP. Notifications are expected to be infrequent.

The total reporting burden includes creation and submission of documents. It covers the greatest amount of reporting burden that might occur for any single creation or submission of a document during any one of the first 3 years following program implementation, i.e., 2000, 2001, and 2002. The total estimated reporting burden reflects the average burden for each reporting activity that might occur in 1 year of this 3-year period.

The total recordkeeping burden is the amount of time needed to store and maintain records. For the purpose of measuring the recordkeeping burden, the year 2002 is used

as the reporting year for which the largest number of records might be stored and maintained. The annual reporting and recordkeeping burdens on producers, handlers, and certifying agents is summarized in Table 4.

Certified operations. The annual burden on certified producers is estimated at 10 hours and \$229. Certified handlers have an estimated burden of 50 hours valued at \$1,189. Certifying agencies have an estimated burden of 700 hours valued at roughly \$18,900.

Exempt operations. The burden on small producers and handlers, who choose to operate as exempt entities, is minimal, 0.5 hour of recordkeeping valued at \$12. Exempt operations are exempt from reporting and recordkeeping burdens. However, small producers and handlers will have to invest some time and review documents to determine whether they qualify for exemption or exclusion. Exempt operations that produce multiingredient products containing less than 50 percent organic ingredient will be required to maintain records documenting the organic ingredients purchased. Since records of purchases would be part of the normal recordkeeping for handlers, we do not consider this a recordkeeping burden.

Based on the projected number of producers (17,150) and handlers (2,150), the total reporting and recordkeeping cost, which captures much of the compliance costs of the rule for this group, is \$5,200,721. We request comment and/or data on the costs that may be imposed by the recordkeeping requirements of the proposed regulation. In addition, we request comment and/or data on the similarities and differences between the current practices of private and state programs and the proposed requirements.

Barriers to Entry—Importers of Organic Products

Currently, there are no federal restrictions on importing organic products to the United States in addition to those regulations applying to conventional products. However, some States require organic products sold within the State to be produced according to the State's standards. Thus, some State programs are barriers to importers. The proposed regulation imposes a national standard that these importers must meet, and may incur some cost. We request comment and/or data on the extent of the organic food imports and the costs that may be imposed on these importers to meet the proposed standards.

Small Business Ramifications

USDA has proposed an 18-month period during which applicants for accreditation would not be billed for hourly services. The rationale for this transition period is to reduce the costs to certifying agents and, thus, increase the prospect that certifying agents, producers, and handlers will be able to afford to participate in the national program. The choice of 18 months is intended to provide sufficient time for parties desiring accreditation to submit their application and prepare for a site evaluation.

USDA has proposed to operate the program partially with appropriated funds, in effect

sharing the cost of the program between taxpayers and the organic industry, to respond to public concerns regarding the effects of the proposed regulation on small businesses. Thousands of comments were received opposing the first proposal's fee provisions with most focusing on the substantial impact on small certifying agents.

Congress has expressed public policy concern with the impacts of regulations on small entities generally and with the impacts on the NOP regulations on small entities particularly. The Small Business Regulatory Enforcement Fairness Act of 1996 and the Regulatory Flexibility Act express Congressional concern regarding regulatory burden on small businesses. The Report from the Committee on Appropriations regarding the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, 2000, includes the following language (U.S. Senate 1999):

"The Committee continues to recognize the importance of organic markets for small farmers and fishermen. The Committee expects the Secretary to construct a national organic program that takes into consideration the needs of small farmers and fishermen."

* * * Furthermore, the Committee expects that of the funding available for the National Organic Program, necessary funds should be used to offset the initial costs of accreditation services, a subsidy necessary due to the lack of expertise in the Department of Agriculture in the areas of organic accreditation and insufficient data on the industry."

Certifying agents applying for accreditation during the first 18 months following the final regulation will face lower direct costs than subsequent applicants. The cost for later applicants for accreditation will be higher because they will have to pay a \$500 application fee and hourly charges for completing their site evaluation. The requirement for accreditation was established in the OFPA in 1990 and the proposed accreditation program was part of the 1997 proposal. Because in this proposal USDA is using appropriated funds to cover some of the costs of initial accreditation during the first 18 months of the program, certifying agents may set lower fees initially benefitting the producers and handlers who are certified during this period.

It is important to note that many small organic operations may not be certified currently. In California, for example, many small farms are registered, but not certified. Even if certifying agents pass on the cost savings of the 18 month period provision to applicants for certification, the cost of certification may be higher than the cost of registration. Hence, becoming a certified operation for small organic producers and handlers may be more costly than the current practices.

The costs imposed on small operations may be mitigated by a \$5000 certification exemption to aid the smallest organic operations. However, these operations are still subject to other requirements of the proposed regulation. To the extent that these requirements differ from their current practices, complying with the national standards may be costly for exempt operations.

In addition, the certification exemption allowed under the proposed regulation includes limits on what an exempt operation may do. Without the certification, small organic operations may not display the USDA seal and may not use a certifying agent's seal. However, we are asking for public comment on whether exempt operations should have the marketing option of selling their products to handlers who can claim the products as organic in multi-ingredient products. If the consumers of organic food view the seals as important information tools on organic food, that is, if consumers of organic products insist on only certified organic products, the inability of small operations to display these seals may prevent them from realizing the price premiums associated with certified organic products.

Industry Composition

The imposition of the national standards may change the composition of the organic industry. Even with the small business exemptions, some small organic operations may choose to exit the industry and small organic operations may also be discouraged from entering the industry, resulting in a higher concentration of larger firms. On the other hand, it may be easier for small operations to comply with certain NOP standards, such as the livestock standards which prohibit confinement production systems and require 100 percent organic feed.

Conclusion

Ideally, the net benefits of the proposed rule would be estimated by employing a welfare analysis. In a welfare model, the quantitative assessment of benefits would be represented by net changes in consumer and producer surplus, *i.e.*, the difference between the willingness to pay (or firm cost structure in the case of producers) and the market price of organic food. These net changes would be estimated using information about the cost structure of the industry, the demand for organic food, and projected shifts in supply and demand resulting from the various factors discussed in the assessment. Although researchers have conducted numerous small-scale studies to determine consumers' willingness to pay for certain organic products (primarily fresh produce) and to identify reasons why conventional food buyers do not choose organic food products (Hammitt, 1990 and 1993; Jolly; Misra *et al.*; Park and Lohr; Weaver *et al.*), the available data are insufficient to support a quantitative assessment of this type. A 1998 review of studies of consumer demand for organic foods concluded, "Attitudes, motives, and willingness to pay for organic products have been measured, but apparently no retail data have been available to estimate own-price, cross-price, and income elasticities." (Thompson 1998).

USDA has identified the entities that may be affected by the proposed rule and has analyzed the anticipated business-associated impacts on them of the rule based on our knowledge of the industry and limited data. We have drawn on industry studies, including studies completed since the 1997 proposed rule was published, and

information provided in comments on the 1997 proposed rule.

The primary benefits from implementation of the proposed rule are improved protection of buyers from a reduction in market confusion including protection from false and misleading claims, and improved access to markets from the reciprocity inherent in national standards. These benefits have not been quantified.

The costs of the proposed regulation are the direct costs for accreditation and the costs of complying with the specific standards in the proposal including the reporting and recordkeeping requirements. Other than accreditation fees, recordkeeping and reporting costs, we did not quantify the magnitude of the compliance costs or the costs of adhering to other provisions of this regulation. We have also not quantified the impact of all these provisions on small business but we believe there impact to be significant.

The direct costs of accreditation if all currently operating certifying agents become certified during the first 18 months following the final rule is approximately \$75,000 to \$100,000. After the first 18 months, the direct cost for accrediting would be approximately \$150,000 to \$238,000. During the 18-month period during which the NOP is not recovering the full costs of accreditation services, the organic industry is being subsidized with appropriated funded derived from the taxpayers. For existing certifying agents compliance costs include costs to become familiar with and adopt NOP standards. The aggregate cost of complying with reporting and recordkeeping requirements of the rule are approximately \$6.8 million. Appropriated NOP funds used to operate the National Organic Program are transfers from the taxpayers to the participants in the organic sector.

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TABLE 1.—ORGANIC FOOD SALES
[\$ billions]

Year	Sales	Sales (1998 dollars)
1990	1.000	1.25
1991	1.250	1.50
1992	1.540	1.79
1993	1.890	2.13
1994	2.310	2.54
1995	2.800	2.99
1996	3.500	3.64

Source: Mergentime and Emerich in *Natural Foods Merchandiser*.

TABLE 2A.—FIRST YEAR CERTIFICATION COSTS, FROM GRAF AND LOHR ANALYSIS
[In dollars]

Certifying agent	Small farm	Medium farm	Large farm	Super farm
CCOF	750	1,650	4,750	51,150
FVO	585	1,624	5,101	51,437
FOG	325	845	2,525	25,525
NOFA-VT	335	535	585	585
OTCO-In	608	1,766	2,517	11,518
OTCO-Out	568	1,498	2,352	11,353
OCIA-WI	315	1,590	6,090	75,090
OCIA-VA	258	320	495	1,745
TDA	90	155	200	515
WSDA	330	1,375	2,800	12,000
NC/SCS	n/a	n/a	n/a	n/a
Average cost	416	1,136	2,742	24,092

Notes:

CCOF—California Certified Organic Farmers

FVO—Farm Verified Organic

FOG—Florida Certified Organic Growers & Consumers

NOFA-VT—Northeast Organic Farming Association—Vermont

OTCO-In—Oregon Tilth Certified Organic, inside Oregon

OTCO-Out—Oregon Tilth Certified Organic, outside Oregon

OCIA-WI—Organic Crop Improvement Association, Wisconsin chapter

OCIA-VA—Organic Crop Improvement Association, Virginia chapter

TDA—Texas Department of Agriculture

WSDA—Washington State Department of Agriculture

NC/SCS—NutriClean/Scientific Certification Systems

Small farm—25 acres with annual sales of \$30,000.

Medium farm—150 acres with annual sales of \$200,000.

Large farm—500 acres with annual sales of \$800,000.

Super farm—3,000 acres with annual sales of \$10,000,000.

TABLE 2B.—SUBSEQUENT YEAR CERTIFICATION COSTS, FROM GRAF AND LOHR ANALYSIS
[In dollars]

Certifying agent	Small farm	Medium farm	Large farm	Super farm
CCOF	425	1,300	4,350	50,550
FVO	510	1,499	4,851	51,187
FOG	325	845	2,525	25,525
NOFA-VT	300	500	550	550
OTCO-In	454	1,611	2,362	11,363
OTCO-Out	424	1,353	2,207	11,208
OCIA-WI	290	1,565	6,065	75,065
OCIA-VA	233	295	470	1,720
TDA	90	155	200	515
WSDA	330	1,375	2,800	12,000
NC/SCS	700	900	1,000	2,000
Average cost	371	1,036	2,489	21,971

Notes:

CCOF—California Certified Organic Farmers

FVO—Farm Verified Organic

FOG—Florida Certified Organic Growers & Consumers

NOFA-VT—Northeast Organic Farming Association—Vermont

OTCO-In—Oregon Tilth Certified Organic, inside Oregon

OTCO-Out—Oregon Tilth Certified Organic, outside Oregon

OCIA-WI—Organic Crop Improvement Association, Wisconsin chapter

OCIA-VA—Organic Crop Improvement Association, Virginia chapter

TDA—Texas Department of Agriculture

WSDA—Washington State Department of Agriculture

NC/SCS—NutriClean/Scientific Certification Systems

Small farm—25 acres with annual sales of \$30,000.

Medium farm—150 acres with annual sales of \$200,000.

Large farm—500 acres with annual sales of \$800,000.

Super farm—3,000 acres with annual sales of \$10,000,000.

TABLE 3.—COSTS OF ACCREDITATION AND CERTIFICATION

Estimated costs to certifying agents during first 18 months	
Application fee ¹	\$0
Site evaluation costs (two person team):	
Per diem (3 to 5 days).	\$480 to \$800
Travel (domestic)	\$1,000 to \$1,200
Hourly charges (not billed).	\$0
Miscellaneous charges (copying, phone, and similar costs).	\$50
Total	\$1,530 to \$2,050
Estimated costs to certifying agents for initial accreditation after first 18 months	
Application fee ¹	\$500
Site evaluation costs (one person):	
Per diem (3 to 5 days).	\$240 to \$400
Travel (domestic)	\$500 to \$600
Hourly charges (24 to 40 hours at \$95/hour)).	\$2,280 to \$3,800

TABLE 3.—COSTS OF ACCREDITATION AND CERTIFICATION—Continued

Miscellaneous charges (copying, phone, and similar costs).	\$50
Total	\$3,070 to \$4,850
Annual review fees for certifying agents (2 to 8 hours at \$95/hour) ² .	\$190 to \$760
Estimated costs to producers for certification ³	
Certification fee (initial certification).	\$800
Certification fee (renewals).	\$730
Estimated costs to handlers for certification ⁴	
Certification fee (initial certification).	\$1,825
Certification fee (renewals).	\$1,665

¹ Nonrefundable fee that will be applied to the applicant's fee for service account.

² Certifying agents are required to submit annual reports to USDA. Review of these reports is expected to range from 2 to 8 hours at an approximate rate of \$95 per hour.

³ Estimated certification fees are calculated from Graf and Lohr 1999 which, for a selection of certification agents, provides certification costs for four hypothetical farm sizes: (1) Small Farm ("Family Farm"): 25 acres, \$30,000 annual sales, 5 hours to certify; (2) Medium Farm ("Cottage Industry"): 150 acres, \$200,000 annual sales, 6 hours to certify; (3) Large Farm ("Commercial Farm"): 500 acres, \$800,000 annual sales, 8 hours to certify; and (4) Super Farm: 3,000 acres, \$10,000,000 annual sales, 16 hours to certify. Our estimated certification fees only include those charged for small and medium farms, because most organic producers fall into these categories as defined by Graf and Lohr. In the 1997 OFRF survey, 90 percent of respondents had gross organic farming income less than \$250,000, with 82 percent less than \$100,000.

The average current certification cost for most organic producers is about \$775 for the first year of certification (\$416 for small and \$1,136 for medium farms) and about \$705 for subsequent years (\$371 for small and \$1,036 for medium farms). Approximately \$25 is added to cover the costs associated with the National Organic Program for an estimated first year certification fee of \$800 and subsequent year certification fee of \$730 for producers. Larger producers could expect higher fees.

⁴ Because Graf and Lohr do not estimate certification fees for handlers, we estimate these fees by applying a ratio of handler-to-producer certification fees from the regulatory impact assessment from 1997. The ratio is 2.28 results in estimated fees of \$1,825 and \$1,665, respectively.

TABLE 4.—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

Type of respondent	Annual hours per respondent	Hourly rate	Annual cost
Certified producer	10	\$24	\$229
Exempt producer	0.5	24	12
Certified handler	50	24	1,189
Exempt handler	0.5	24	12
State certifying agency	696	27	18,778
Private or foreign certifying agency	700	27	18,893

Note: Estimates derived from Paperwork Reduction Act of 1995 analysis.

Appendix B.—Unfunded Mandates Reform Act

This proposed rule has been reviewed under the Unfunded Mandates Reform Act (P.L.104-4). The Act requires that agencies prepare a qualitative and quantitative assessment of the anticipated costs and benefits before proposing any rule that may result in annual expenditures by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million (adjusted annually for inflation) in any one year. According to the Act, the term *Federal mandate* means any provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or tribal governments, or the private sector, except a duty arising from participation in a voluntary Federal program.

The National Organic Foods Production Act (OFPA) of 1990 mandates that the Secretary develop a National Organic Program (NOP) to accredit eligible governing

State officials or private persons as certifying agents who would certify producers or handlers of agricultural products that have been produced using organic methods as provided for in the OFPA. The OFPA also permits a governing State official to voluntarily establish a State organic certification program if the program is approved by the Secretary and meets the requirements of the OFPA. The OFPA does not require that States establish their own organic certification programs or that State, local or tribal governments, or the private sector, become accredited; therefore, the OFPA is not subject to the Unfunded Mandates Reform Act because it is a voluntary program.

Although USDA has determined that this proposed rule is not subject to the Unfunded Mandates Reform Act, USDA has sought to consider the rule's impact on various entities. USDA prepared a Regulatory Impact Assessment (RIA) that is discussed in the section titled "Executive Order 12866" (also

attached as an appendix to this proposed regulation). The RIA consists of a statement of the need for the proposed action, an examination of alternative approaches, and an analysis of the benefits and costs. Much of the analysis is necessarily descriptive of the anticipated impacts of the proposed rule. Because basic market data on the prices and quantities of organic goods and services and the costs of organic production is limited, it is not possible to provide quantitative estimates of all benefits and costs of the proposed rule. The cost of fees and recordkeeping proposed by the USDA are quantified, but the anticipated benefits are not. Consequently, the analysis does not contain an estimate of net benefits.

The analysis employed in reaching a determination that this proposed rule is the least costly and least burdensome to the regulated parties is discussed in the sections titled "The Regulatory Flexibility Act and the Effects on Small Businesses" and "Paperwork Reduction Act of 1995." The

proposed rule has been designed to be as consistent as possible with existing industry practices, while satisfying the specific requirements of the OFPA.

We have had numerous occasions to communicate with various entities during the development of the proposed rule; States, for example. Currently there are 27 States with some standards governing the production or handling of organic food and 13 States with organic certifying programs. Representatives of State governments have participated in public meetings with the NOSB, while the NOP staff has made presentations, received comments, and consulted with States and local and regional organic conferences, workshops, and trade shows. States have been actively involved in training sessions for organic inspectors; public hearings concerning standards for livestock products during 1994; a national Organic Certifiers meeting on July 21, 1995; a USDA-hosted meeting on February 26, 1996; a State certifiers meeting in February 1999; and an ISO 65 assessment training session for certifiers in April-May 1999. It is unknown at this time how many States, if any, might voluntarily establish their own organic certification programs pursuant to the OFPA and the regulations.

Appendix C.—The Regulatory Flexibility Act and the Effects on Small Businesses

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (Act) requires agencies to consider the economic impact of each proposed rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose is to fit regulatory actions to the scale of businesses subject to the action.

In the first proposal published in December 1997, the initial Regulatory Flexibility Analysis (RFA), describing the impact of the National Organic Program and evaluating the alternatives, was written with guidance from the U.S. Small Business Administration (SBA). The RFA of this proposal was written following consideration of comments received in response to the first proposal, other information that has become available since the first proposal, the Regulatory Impact Assessment (RIA) that is discussed in the section entitled "Executive Order 12866" (also attached as an appendix to this proposal), and the information collection burden discussed in the section entitled "Paperwork Reduction Act of 1995" (PRA).

Reasons for Proposal

Currently, organic certification is voluntary and self-imposed. Members of organic industries across the U.S. have experienced numerous problems marketing their organically produced and handled agricultural products. Inconsistent and conflicting organic production standards may have been an obstacle to the effective marketing of organic products. There are currently 36 private and 13 State organic certification agencies (certifying agents) in the United States, each with its own standards and identifying marks.

Some existing private certifying agents are concerned that States might impose registration or licensing fees which would limit or prevent private certification activities in those States. Labeling problems have confronted manufacturers of multi ingredient organic food products containing ingredients certified by different certifying agents because reciprocity agreements have to be negotiated between certifying agents. Consumer confusion may exist because of the variety of seals, labels, and logos used by certifying agents and State programs. Also, there is no industry wide agreement on an accepted list of substances that should be permitted or prohibited for use in organic production and handling. Finally, a lack of national organic standards may inhibit organic producers and handlers in taking full advantage of international organic markets and may reduce consumer choices in the variety of organic products available in the marketplace.

To address these problems in the late 1980's, the organic industry attempted to establish a national voluntary organic certification program. At that time, the industry could not develop consensus on the standards that should be adopted, so Congress was petitioned by the Organic Trade Association to establish national standards for organic food and fiber products.

Recently, the Organic Trade Association published American Organic Standards, Guidelines for the Organic Industry (AOS). However, not all participants in the organic industry elected to participate in developing the AOS. Many certifying agents preferred to wait for implementation of the National standards, and some certifying agents disagree with portions of the AOS. For these reasons, the USDA is proposing a regulation for the National Organic Program.

Legal Basis for and Objectives of Proposal

In 1990, Congress enacted the Organic Foods Production Act of 1990, as amended (7 U.S.C. 6501 *et seq.*) (OFPA). The OFPA requires all agricultural products labeled as "organically produced" to originate from farms or handling operations certified by a State or private agency that has been accredited by USDA.

The purposes of the OFPA, set forth in section 2102 (7 U.S.C. 6501), are to: (1) Establish national standards governing the marketing of certain agricultural products as organically produced products; (2) assure consumers that organically produced products meet a consistent standard; and (3) facilitate commerce in fresh and processed food that is organically produced. The National Organic Program, which this rule proposes, is the result of the OFPA.

Applicability of Proposal

This proposal will directly affect three sectors of the organic industry: certifying agents, producers, and handlers. The OFPA provides for the collection of reasonable fees by USDA from producers, handlers, and certifying agents who participate in the national program. This proposal will impose direct costs on certifying agents in the form of a fee paid to the Federal Government for USDA accreditation. This proposal does not

impose direct costs in the form of fees on producers and handlers. Certifying agents will establish a fee schedule for their certification services for producers and handlers. All three sectors are subject to indirect costs of compliance.

The term, "certifying agent," means the chief executive officer of a State or, in the case of a State that provides for the statewide election of an official to be responsible solely for the administration of the agricultural operations of a State, such official and any person (including private entities) who is accredited by the Secretary as a certifying agent for the purpose of certifying a farm or handling operation as a certified organic farm or handling operation. The term, "producer," means a person who engages in the business of growing or producing food or feed. The term, "handler," means any person engaged in the business of handling agricultural products, excluding final retailers of agricultural products that do not process agricultural products. Subpart B, section 205.101 in the proposed regulation provides information about exemptions and exclusions from certification.

According to the most complete data available to USDA's Agricultural Marketing Service (AMS), there are 49 certifying agents (36 private and 13 State) in the U.S. Over half of the private and State certifying agents certify both producers and handlers, while the others certify only producers. Over three-fourths of private and State certifying agents each certify fewer than 150 producers and 20 handlers. The number of certifying agents has remained fairly stable between 40 and 50 for some years, with entries and exits tending to offset each other. The National Organic Program staff anticipates that, in addition to the 49 domestic certifying agents, 10 foreign certifying agents may seek accreditation during the initial phase of the program.

It is more difficult to establish the number of organic producers. Organic farming was not distinguished from conventional agriculture in the 1997 Census of Agriculture. There are sources which give insight into the number of producers. The Organic Farming Research Foundation (OFRF), a California-based nonprofit organization, has conducted three nationwide surveys of certified organic producers from lists provided by cooperating certifying agents. The most recent survey applies to the 1997 production year.¹ OFRF sent its 1997 survey to 4,638 names and received 1,192 responses. Because OFRF did not obtain lists from all certifying organizations or their chapters (55 out of a total of 64 identified entities provided lists), their list count is likely an understatement of the number of certified organic producers. Note that the estimated number of organic producers includes only certified organic farms. Comments filed in response to the first proposal and studies indicate that the total number of organic farms is higher.

¹ Organic Farming Research Foundation. 1999. Final Results of the Third Biennial National Organic Farmers' Survey. Santa Cruz, CA.

Dunn has estimated the number of certified organic producers in the U.S.^{2,3} Dunn's 1995 work, a USDA study, estimated the number of certified producers at 4,060 in 1994; this estimate was used in the first proposal. Dunn's 1997 work reported 4,060 certified organic farms in 1994 and 4,856 in 1995.

Data collected by AMS indicate that the number of organic farmers increased about 12 percent per year and the number of organic handlers increased at about 11 percent per year during the period 1990 to 1994. OFRF survey efforts indicate that growth has continued, although it is not clear whether the growth rate has changed. Similarly, growth in retail sales, the addition of meat and poultry to organic production, and the possibility of increased exports suggest that the number of operations has continued to increase. Lacking an alternative estimate of the growth rate for the number of certified organic producers, we use the average growth rate of about 14 percent from Dunn's 1997 study. The true rate of growth could be higher or lower. Applying the 14-percent growth rate to Dunn's estimate of certified producers in 1995 gives an estimate of 8,200 organic producers for 1999.

An adjustment is needed to account for the number of producers who are practicing organic agriculture but who are not certified and who would be affected by this proposal. We assume that the number of organic but not certified producers in 1999 is about 4,000. This assumption is based on very limited information about the number of registered but not certified organic producers in California in 1995. Thus, the total number of organic producers used in assessing the impact of the rule is 12,176 in 1999.

Little information exists on the numbers of handlers and processors. USDA has estimated that there were 600 entities in this category in 1994. In California, there were 208 registered organic processed food firms in 1995 and 376 in 1999, a growth rate of 20 percent.⁴ We assume that this growth rate is applicable to the U.S. and project 1,250 handlers in 1999. Again, the rate of growth could be higher or lower.

SBA Definitions of Small Entities

Small business size standards, Standard Industrial Code (SIC) (13 CFR part 121), are developed by an inter-agency group, published by the Office of Management and Budget, and used by SBA to identify small

businesses. These standards represent the number of employees or annual receipts constituting the largest size that a for-profit enterprise (together with its affiliates) may be and remain eligible as a small business for various SBA and other Federal Government programs.

Small businesses in the agricultural services sector, such as certifying agents, include firms with average annual revenues of less than \$5 million (SIC Division A Major Group 7). Producers with crop production (SIC Division A Major Group 1) and annual average revenues under \$500,000 are small businesses. Producers with livestock or animal specialties are also considered small if annual average revenues are under \$500,000 (SIC Division A Major Group 2), with the exception of custom beef cattle feedlots and chicken eggs, which are considered small if annual average revenues are under \$1,500,000. In handling operations, a small business has fewer than 500 employees (SIC Division D Major Group 20).

Based on SBA's small business size standards for the agricultural services sector, it is not likely that many, if any, of the 49 domestic certifying agents have annual revenue greater than \$5 million. Based on anecdotal information, only a few private, for-profit, certifying agents might be categorized as a large business. All private, non profit, and State certifying agents would be considered small by SBA's standards. Even if State certifying agents do not exceed the revenue threshold, they would not be considered to be small entities under the Act if the agents are an arm of state government. Only government jurisdictions with populations under 50,000 are considered to be small entities under section 601(5) of the Act.

Based on SBA's small business size standards for producers, it is likely that almost all organic producers would be considered small. The OFRF survey asked for the producer's total gross organic farming income during 1997. Only 35 (less than 3 percent) of the survey respondents reported gross income greater than \$500,000, the SBA's cutoff between small and large businesses. Over 70 percent reported gross income of less than \$50,000. The OFRF survey does caution readers about potential survey "errors." It is particularly important to emphasize potential "non-response error," that is, it is unknown if those who responded

to the survey accurately represent the entire population of certified organic growers. Also, some producers combine organic and conventional production on the same operation, some with total sales that may exceed \$500,000. However, it is likely that a majority of organic producers would be considered small.

It is also likely that the vast majority of handlers would be considered small, based on SBA's small business size standards for handlers. Based on informal conversations with organic certifying agents, about 25 (about 2 percent) of the estimated 1,250 organic handlers have more than 500 employees. This includes firms that handle or process both organic and conventional foods.

Costs of This Proposal

Several requirements to complete this RFA overlap with the RIA and the PRA. In order to avoid duplication, we combine some analyses as allowed in section 605(b) of the Act. This RFA provides information specific to small entities, while the RIA or PRA should be referred to for more detail. For example, the RFA requires an analysis of the proposed rule's costs to small entities. The RIA provides an analysis of the benefits and costs of this proposal. This RFA uses the RIA information to estimate the impact on small entities. Likewise, the RFA requires a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule. The PRA section estimates the reporting and recordkeeping (information collection) requirements that would be required by this proposal from individuals, businesses, other private institutions, and State and local governments. The burden of these requirements is measured in terms of the amount of time required of program participants and its cost. This RFA uses the PRA information to estimate the burden on small entities.

The estimated direct costs of accreditation for certifying agents and certification for producers and handlers under the first proposal issued in December 1997 and this proposal are shown in table 1 and discussed in the following sections. More specific details regarding these costs are found in the RIA.

TABLE 1.—ESTIMATED DIRECT COSTS OF ACCREDITATION AND CERTIFICATION

	First proposal		This proposal	
	1st year cost	2nd year cost	1st year cost	2nd year cost
Certifying Agents:				
Accreditation application fee	\$640	\$640	\$0	\$0
USDA administrative fee	2,000	2,000	0	0
Estimated site evaluation fee	3,500	¹	1,530 to ³ 2,050	¹
Annual review fee		²		² 190 to 760

² Dunn, Julie Anton. 1995. Organic Food and Fiber: An Analysis of 1994 Certified Production in the United States. U.S. Department of Agriculture, Agricultural Marketing Service.

³ Dunn, Julie Anton. 1997. AgriSystems International Reports Certified Organic Production in the United States: Half a Decade of Growth. AgriSystems International: Wind Gap, PA.

⁴ California Department of Health Services (DHS). 1995. Report on the Registration of California Organic Processed Food Firms. Sacramento: State of California. September 1999 figures obtained via personal communication with California DHS.

TABLE 1.—ESTIMATED DIRECT COSTS OF ACCREDITATION AND CERTIFICATION—Continued

	First proposal		This proposal	
	1st year cost	2nd year cost	1st year cost	2nd year cost
Total Fees	6,140	min. 2,640	min. 1,530	min. 190
Producers:				
Estimated certification fee ⁴	413	413	800	730
USDA fee	50	50	0	0
Total Fees	463	463	800	730
Handlers:				
Estimated certification fee ⁴	943	943	1,825	1,665
USDA fee	500	500	0	0
Total Fees	1,443	1,443	1,825	1,665

¹ Should certifying agents wish to become accredited in additional areas for which they have not been accredited previously, site evaluation fees will be charged.

² First proposal: Included in application and administrative fees. This proposal: Certifying agents are required to submit annual reports to USDA. Review of these reports is expected to range from 2 to 8 hours at an approximate rate of \$95 per hour.

³ During the first 18 months, site evaluation for initial accreditation will involve two reviewers. One reviewer would come from the Quality Systems Certification Program audit staff and would be familiar with ISO Guide 65 verification; the other reviewer would come from the National Organic Program staff and would be familiar with requirements of the organic program. The two would conduct the site evaluation jointly. We anticipate only one reviewer would be required after the 18-month transition period. The estimated site evaluation fee shown here includes per diem and travel costs for two reviewers plus miscellaneous charges related to accreditation. Site evaluations for smaller certifying agents are estimated to take 3 days, with 5 days for larger certifying agents.

For the first 18 months after implementation of the NOP, hourly rates will not be charged to certifying agents for accreditation. The estimated fee shown here includes only travel and per diem expenses. At an approximate rate of \$95 per hour, hourly charges would add an estimated \$4,560 to \$7,600 for 2 reviewers during the first 18 months, and \$2,280 to \$3,800 for 1 reviewer after the first 18 months or for renewal of accreditation.

⁴ First proposal: Estimated certification fees at that time were based on the average of fees charged by a representative group of certifying agents (private non-profit, private for-profit and a State agency).

This proposal: Estimated certification fees are calculated from a 1999 study by Graf and Lohr⁵ which, for a selection of certification agents, provides certification costs for four hypothetical farm sizes: (1) Small Farm ("Family Farm"): 25 acres, \$30,000 annual sales, 5 hours to certify; (2) Medium Farm ("Cottage Industry"): 150 acres, \$200,000 annual sales, 6 hours to certify; (3) Large Farm ("Commercial Farm"): 500 acres, \$800,000 annual sales, 8 hours to certify; and (4) Super Farm: 3,000 acres, \$10,000,000 annual sales, 16 hours to certify. Our estimated certification fees only include those charged for small and medium farms, because most organic producers fall into these categories as defined by Graf and Lohr. In the 1997 OFRF survey, 90 percent of respondents had gross organic farming income less than \$250,000, with 82 percent less than \$100,000.

The average current certification cost for most organic producers is about \$775 for the first year of certification (\$416 for small and \$1,136 for medium farms) and about \$705 for subsequent years (\$371 for small and \$1,036 for medium farms). An estimated \$25 is added to cover the costs associated with the National Organic Program for an estimated first year certification fee of \$800 and subsequent year certification fee of \$730 for producers. Larger producers could expect higher fees.

Because Graf and Lohr do not estimate certification fees for handlers, we estimate these fees by applying the December 1997 ratio of handler-to-producer certification fees, 2.28, to the estimated first and subsequent year certification fees for producers, resulting in fees of \$1,825 and \$1,665, respectively.

Direct Costs to Certifying Agents

We have identified 36 private certifying agents and 13 State programs providing certification. These 49 domestic entities are considered likely applicants during the first 12 months, as are an estimated 10 foreign certifying agents. An unknown number of new entrants to the certifying business may also apply. However, over the last 10 years, the number of certifying agents does not appear to have grown significantly, with the net effect of entries and exits maintaining a population of U.S.-based certifying agents at about 40 to 50. Of the 49 domestic certifying agents, based on information discussed previously, we estimate that the 36 private certifying agents are small.

In order to identify the certifying agents that might be expected to face more significant impacts as a result of this proposal, we analyzed the amount of revenues from certification fees received by

certifying agents. Total certification fees collected by the certifying agents in 1994 ranged from about \$2,500 to about \$400,000, with most certifying agents clustered around the low or high end of this range. This amount is based on information collected by AMS from a sample of 16 private and State certifying agents for certification fees collected in 1994. To determine a cutoff point for small certifying agents, the State certifying agents were eliminated from the sample because these agents are an arm of State government and are not considered small entities. Of the remaining 11 private certifying agents, 6 (or 55 percent) collected less than \$25,000 each in total certification fees, and the other 5 (45 percent) each collected more than \$200,000. Based on this information and knowledge of the organic industry, for purposes of analyzing the cost of accreditation, we estimate that about 55 percent of private certifying agents are small with total annual revenue from certification of less than \$25,000.

Certification fees probably do not constitute total income for most private certifying agents and, thus, are not a complete measure of economic size. Some

certifying agents also earn revenue from a number of other sources, such as sale of publications, membership dues, training workshop and conference fees, farmers markets, grants, or donations.

Certifying agents will be assessed for the actual time and travel expenses necessary for the National Organic Program to perform accreditation services. The National Organic Program will charge the same hourly fees as are charged for the voluntary, fee-for-service program provided by AMS to certification bodies requesting conformity assessment to the International Organization for Standardization (ISO) Guide 65, "General Requirements for Bodies Operating Product Certification Systems." We expect that at the time the National Organic Program's final rule is implemented, the fees will be approximately \$95 per hour, with higher overtime and holiday rates. Certifying agents will be charged for travel, per diem, and other related costs associated with accreditation. Applicants for accreditation will be required to pay at the time of application a nonrefundable fee of \$500, which is applied to the applicant's fee for services account. This fee is credited against

⁵ Graf, Anita and Luanne Lohr. 1999. Analysis of certification program costs. Working Paper, Fund for Rural America project, Market Development for Organic Agriculture Projects, Grant No. 97-36200-5.

any subsequent costs of accreditation arising from the site evaluation.

During the first 18 months after the National Organic Program has been implemented, USDA will not impose hourly charges on certifying agents. The direct costs for certifying agents to obtain accreditation will be limited to per diem and transportation costs for the site evaluation, which is required every 5 years. We estimate these costs to be \$1,530 for a small certifying agent and \$2,050 for a larger certifying agent. These estimates are based on, for small and larger certifying agents, two reviewers with 3 and 5 days of per diem, \$500 to \$600 in transportation costs, and \$50 in miscellaneous charges related to accreditation.⁶ In subsequent years, certifying agents will be required to submit an annual report. Review of this report is anticipated to range from 2 to 8 hours at the ISO Guide 65 hourly rate. If certifying agents wish to become accredited in additional areas for which they were not accredited previously, site evaluation fees will be charged.

After the first 18 months of the National Organic Program, USDA estimates that the costs of a site evaluation visit, required every 5 years, could be \$3,070 for small certifying agents and \$4,850 for larger certifying agents. These estimates are based on, for small and larger certifying agents, one reviewer with 3 and 5 days of per diem, \$500 to \$600 in transportation costs, \$50 in miscellaneous charges related to accreditation, and 24 to 40 hours (3 to 5 work days) at an anticipated maximum hourly rate under ISO Guide 65 of \$95. Higher hourly rates will be charged for overtime and for work on holidays.

The cost of a site evaluation will vary with the cost of travel from the auditor's work station to the applicant's place of business. Auditors live in different parts of the country, and travel costs might be reduced when the distance traveled is reduced. The lowest cost airfare would be used whenever possible. In some cases, site evaluations might be grouped geographically in order to reduce travel expenses. The per diem rate will also vary depending on the rate set for the certifying agent's location as established by the General Services Administration.

Several factors will influence the amount of time needed to complete an accreditation audit. An operation in which documents are well organized and that has few nonconformities within the quality system

will require less time for an audit than an organization in which documents are scattered and there are many nonconformities.⁷ Similarly, in a follow up audit, operations that lack organization in their documents and that had a large number of nonconformities during previous audits will require a greater amount of time. The scope of a follow up audit is to verify the correction of nonconformities and to evaluate the effectiveness of the corrections. Certifying agents are able to control these cost factors by making certain that documents are well organized and by educating themselves about quality systems.

The complexity of an certification agency's organization also will affect the time needed to complete an audit. An agency with a central office in which all certification activities take place will require less time for document review and site evaluation than a chapter organization or a business structured so that responsibility for making certification decisions is delegated outside of the central office. In the latter cases, the auditors' document review would require additional time and site evaluation that would extend from the central office to one or more of the chapters or to the site to which the certification decision making is delegated.

Other factors determine the amount of time needed to complete an accreditation audit. For an agency with numerous clients, auditors may need to spend more time reviewing client files or examining business operations than they would have to spend for a smaller agency. Audit of an agency with a large number of processor clients may require an extended amount of time to follow audit trails, confirm that organic ingredients remain segregated from nonorganic ingredients, and establish that foreign-produced ingredients originate from approved entities. Finally, the complexity of the agricultural practices certified could influence the amount of time necessary to complete an accreditation audit. An agency whose certification covers only producers who grow and harvest one crop per field per year, such as wheat or sugar beets, could quickly be audited. An agency whose producers grow several different crops per field per year or an agency that certifies producers of crops and livestock as well as handlers would require a greater amount of time.

All of these factors will impact both small and large certifying agents. A small certifying agent could be assumed to have a less complex organization or have fewer clients, and, thus, potentially less time would be necessary for review. However, other factors, such as the degree of paperwork organization or the complexity of the agricultural practices certified, may influence the time needed for review for any size of business.

Comments from the first proposal indicate that the average accreditation cost for a certifying agent may range from \$3,000 to \$5,000 per year for small to medium-size certifying agents to less than \$10,000 per year for the largest certifying agents.

⁷ Adequate advance notice will be given to organizing agents to allow them the opportunity to organize their records prior to the audit and minimize the costs of accreditation.

Currently, relatively few certifying agents have third party accreditation because accreditation of certifying agents is voluntary. Fetter reports that in a sample of 18 certification programs, selected to include six large, private programs, six smaller private programs, and six State programs, four programs were accredited and one had accreditation pending.⁸ All of these were large private certifying agents. Three of the certifying agents identified by Fetter as accredited requested ISO Guide 65 assessments by USDA and have been approved for selling organic products into the international market. Those certifying agents currently accredited by third parties will likely pay less for USDA accreditation because their documents are organized and they have fewer nonconformities.

Those certifying agents who have been operating without third party accreditation will face new costs—the costs of accreditation—under this proposal. Compared to the direct costs of \$3,000 to \$5,000 per year indicated by the commenters, the direct costs of USDA accreditation will be smaller, with estimated site evaluation fees (covering 5 years) ranging from \$3,070 to \$4,850 for the first year and an annual review fee ranging from \$190 to \$760 for subsequent years. Furthermore, the direct costs would be substantially less for those certifying agents obtaining accreditation during the first 18 months while USDA does not impose an application fee or hourly charges and limits direct costs to travel and per diem costs.

It is expected that all certifying agents will set their fee schedule to recover costs for their certification services, including the costs of accreditation. The larger the number of clients per certifying agent, the more fixed costs can be spread out. It is possible, however, that small certifying agents could be significantly impacted by this proposal and may not be able to continue in business from a financial standpoint.

Projected Reporting, Recordkeeping, and Other Compliance Requirements of Certifying Agents

In addition to the direct costs, the regulation will impose administrative costs on certifying agents for reporting, recordkeeping, residue testing, and other compliance requirements. The actual amount of the additional administrative costs that would be imposed by the final rule is expected to be different for those entities that would begin their activities only after the national program is implemented. Certifying agents that currently are active in the organic industry already perform most of these administrative functions; therefore, the additional costs to them would depend upon the extent to which their current practices are different from the requirements of the final regulation. Projected reporting, recordkeeping, and other compliance requirements of certifying agents are discussed in greater detail in the PRA and the RIA.

⁸ Fetter, Robert T. 1999. Economic Impacts of Alternative Scenarios of Organic Products Regulation. Senior Honors Thesis. University of Massachusetts, Amherst, MA.

⁶ During the first 18 months, site evaluation for initial accreditation will be conducted jointly by two reviewers. Two reviewers offers: (1) anticipated faster turn-around; (2) different areas of expertise—one reviewer would come from the Quality Systems Certification Program audit staff and would be familiar with ISO Guide 65 verification, while the other reviewer would come from the National Organic Program staff and would be familiar with the requirements of the program; and (3) consistency with the organic industry's desire to have reviewers from both areas of expertise during ISO Guide 65 assessments. AMS would consider sending one reviewer, rather than two, for the site evaluation of small certification agents if an individual possessing both reviewing skill and knowledge of the NOP is available. We anticipate only one reviewer would be required after the 18-month transition period.

Costs to Producers and Handlers

Under this proposal, USDA will not impose any direct fees on producers and handlers. Certifying agents will establish a fee schedule for their certification services that will be filed with the Secretary and posted in a place accessible to the public. Certifying agents will provide all persons inquiring about the application process with a copy of their fees. The certifying agent may only charge those fees that it has filed with the Secretary. Furthermore, the certifying agent will provide each applicant with an estimate of the total cost of certification and an estimate of the annual costs of updating

the certification. However, the certifying agent may require applicants to pay at the time of application a nonrefundable fee of no more than \$250 which must be applied to the applicant's fee for services account.

Currently, supply and demand for certification services determine the fees charged in most areas. Some States charge minimal fees for certification and instead subsidize operating costs from general revenues. According to separate studies by Fetter, and Graf and Lohr, the majority of certifying agents structure their fee schedules on a sliding scale based on a measure of size, usually represented by the client's gross sales

of organic products but sometimes based on the acres operated. Some certifying agents charge an hourly rate for inspection and audit services.

Graf and Lohr have applied fee schedules provided by nine certifying agents to four hypothetical farms—small, medium, large, and a super farm. They define "small" as a 25-acre farm with annual sales of \$30,000 that would take 5 hours to certify. Note that our alternative definition of small (under \$5,000) is different. Table 2 shows the total first-year cost and subsequent-year cost for certification for small farms; the RIA shows detail on other size farms.

TABLE 2.—CERTIFICATION COSTS AMONG A SELECTION OF CERTIFYING AGENTS

[For a small farm: 25 acres, \$30,000 annual sales, 5 hours to certify]

Certifying agent	Total cost to certify in first year	Total cost to certify in subsequent years
California Certified Organic Farmers	\$750	\$425
Farm Verified Organic	585	510
Florida Certified Organic Growers and Consumers	325	325
Northeast Organic Farming Association—Vermont	335	300
Oregon Tilth Certified Organic:		
—Inside Oregon	608	454
—Outside Oregon	568	424
Organic Crop Improvement Association:		
—Wisconsin chapter	315	290
—Virginia chapter	258	233
Texas Department of Agriculture	90	90
Washington State Department of Agriculture	330	330
NutriClean/Scientific Certification Systems	n/a	700
Average cost	416	371

The Texas Department of Agriculture program is the low-cost certifying agent. The high-cost certifying agent differs from first-year to subsequent-year certification. Graf and Lohr's study indicates that even small farms require significant time for the certification process and this time does not increase proportionately as farm size increases. None of these certification programs mentions costs for residue testing which the National Organic Program will require in the form of preharvest testing when there is reason to believe that agricultural products have come in contact with prohibited substances. Preharvest testing is expected to be infrequent. Certifiers will recover the costs of preharvest testing through explicit charges to the producer whose crop is tested, or through a generally higher fee structure that spreads the expected costs of tests over all clients.

Certifying agents will continue to set their own fee schedules under the organic program. Certifying agents will have to set fees to cover any net additional costs of doing business under the National Organic Program. Accreditation and administrative costs are incremental costs to existing certifying agents' businesses. Some certifying agents might drop their third party accreditation saving perhaps \$3,000 to \$5,000 per year, but most certifying agents are not currently paying for accreditation.

This proposal imposes no requirements that would cause certifying agents that are presently using a sliding scale type fee

schedule to abandon their current fee system. Certifying agents could recover their net additional costs by increasing their flat fee component, their incremental charges, or both. Because accreditations are renewed only every 5 years, certifying agents will have 5 years to recover their net new costs.

Certifying agents who become accredited during the first year of the program would have fewer direct costs to recover, because they will not be charged the application fee and hourly charges for accreditation services.

The OFPA established a small farmer exemption from certification and submission of organic plans for small producers with a maximum of \$5,000 in gross sales of organic products. For purposes of the exemption, the OFPA defines a "small farmer" as those who sell no more than \$5,000 annually in value of agricultural products. In this proposal, we have clarified that the exemption applies to those who sell no more than \$5,000 annually in value of organic products.⁹ According to

⁹ We asked for comments on the first proposal as to whether the current statutory limitation of \$5,000 for exemption from certification should be raised to \$10,000 or to another amount and why such an increased monetary limitation for exemption from certification would be appropriate. Few commenters offered recommendations as to a maximum sales volume to exempt producers. Amounts ranged from \$2,000 to \$50,000, with a few suggesting \$10,000 and \$20,000 exemptions. These proposed exemption levels and justifications in comments received are not sufficiently consistent enough for us to recommend changing the statute

the OFRF survey, 27 percent of currently certified farms that responded to the survey would fall under this exemption. This percentage does not take into account those organic farms that are not currently certified by a private or State certifying agent. A study of California organic farms found that, of all organic farms¹⁰ in 1994–95, about 66 percent have revenues less than \$10,000.¹¹ If California is representative and the distribution within the sub-\$10,000 category is uniform, then a third of the farms would be classified as small for purposes of the statutory exemption with annual sales less than \$5,000. Based on the California study and the OFRF survey results, we estimate that between 25 and 33 percent of organic producers are small and would qualify for exemption from the certification requirements.

We have estimated that there are between 3,000 and 4,000 small organic producers that will be exempt from certification. These producers would be required to comply with

requirement of the \$5,000 maximum sales volume exemption.

¹⁰ California State law requires organic farmers to register with the State. Certification is voluntary at the current time.

¹¹ Klonsky, Karen, and Laura Tourte. 1998. Statistical Review of California's Organic Agriculture, 1992–95. Report prepared for the California Department of Food and Agriculture Organic Program. Cooperative Extension, Department of Agricultural Economics, University of California, Davis.

the production and handling standards and labeling requirements set forth under the National Organic Program. We anticipate that this exemption will be used primarily by small market gardeners and hobbyists who sell produce and other agricultural products at farmers markets and roadside stands to consumers within their communities. By being exempt from certification, the current certification costs (table 2) estimated at an average \$416 for the first year and an average \$370 for subsequent years have been eliminated.

Exempt producers will be allowed to market their products as organically produced without being certified by a certifying agent. Products marketed by exempt producers cannot be represented as certified organic or display the USDA organic seal. Products produced or handled on an exempt operation may be identified as organic ingredients in a multiingredient product produced by the exempt operation, but they may not be identified as organic in a product processed by others. These limitations may discourage some small producers from seeking exemption, who instead may choose to become certified. In this case, the costs of certification would apply. The value associated with having organic certification may outweigh the costs of certification.

Those currently receiving voluntary certification will likely see a modest increase as the certifying agent passes on its cost incurred under the National Organic Program. Those not currently receiving certification and producing over \$5,000 annually in organic products will be required to become certified, and they will incur the actual costs of certification.

We have estimated that there about 98 percent of the 1,250 organic handlers are small. A handling operation or a portion of a handling operation is exempt from certification requirements if it has annual gross sales of less than \$5,000; is a retail food establishment that handles organically produced agricultural products but does not process them; handles agricultural products that contain less than 50 percent organic ingredients by weight of finished product; or does not use the word, "organic," on any package panel other than the information panel if the agricultural product contains at least 50 percent organic ingredients by weight of finished product. A handling operation or specific portion of a handling operation is excluded from certification if it handles packaged certified organic products that were enclosed in their packages or containers prior to being acquired and remain in the same package and are not otherwise processed by the handler, or it is a retail food establishment that processes or prepares on its own premises raw and ready-to-eat food from certified organic products. Otherwise, to be certified organic, handlers must pay for certification fees estimated at \$1,800 per year and fulfill recordkeeping requirements.

In order to identify handlers that might be expected to face more significant impacts as a result of this proposal, we attempted to analyze handlers' revenue from organic sales. Sales data indicate that gross sales of organic

production total less than \$500,000 per firm for most certified handlers. Information from the California DHS, where State law requires organic processors to register, gives some indication of the size distribution. Of the 208 processors registered with the State in 1995, 80 firms (38 percent) reported gross sales of \$50,000 or less, and 50 firms (24 percent) had gross sales exceeding \$500,000. In mid-September 1999, 376 processors were registered with the State, with 107 firms (28 percent) reporting gross sales of \$50,000 or less and 112 firms (30 percent) reporting gross sales exceeding \$500,000. We use this California information to estimate that 25 to 30 percent of handlers have gross sales of \$50,000 or less and could be significantly impacted by this proposal. Information needed to estimate the number of exempt or excluded handlers is not available.

Some States, such as Texas and Washington, charge producers and handlers nominal fees for certification, and it is possible that more States might provide certification services as the National Organic Program is implemented. Other States, such as Minnesota, have cost-share programs to help offset costs for organic producers.

Projected Reporting, Recordkeeping, and Other Compliance Requirements for Producers and Handlers

In addition to the fees for certification, the regulation will impose administrative costs on producers and handlers for reporting, recordkeeping, residue testing, and other compliance requirements. The actual amount of the additional administrative costs that would be imposed by the final rule is expected to be different for those entities that would begin their activities only after the national program is implemented. Producers and handlers who currently are active in the organic industry already perform most of these administrative functions; therefore, the additional costs to them would depend upon the extent to which their current practices are different from the requirements of the final regulation. Projected reporting, recordkeeping, and other compliance requirements of certifying agents are discussed in greater detail in the PRA and the RIA.

Federal Rules

No other burdens are expected to fall upon the organic industry as a result of overlapping Federal rules. This proposed regulation would not duplicate, overlap or conflict with any existing Federal rules. In preparing this proposed regulation, AMS consulted other Federal agencies such as the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), the Bureau of Alcohol, Tobacco and Firearms (ATF), and the USDA's Food Safety and Inspection Service (FSIS) to ensure that this proposed regulation would complement existing regulations.

Alternatives to This Proposal

We believe that our proposed regulation could have a significant impact on a substantial number of small businesses. However, we have considered several options with the intention of mitigating negative economic impacts of the fees. We did not

consider alternatives, beyond the previously discussed exemptions, that would mitigate the indirect costs of this rule on small entities. The following options were considered by AMS prior to and during the development of this proposal:

Option 1: First Proposal Issued December 1997

The first proposal suggested a fee for direct services model which combined a fixed fee for all farmers, handlers, and certifying agents, with a variable fee for certain direct services provided by AMS in the accreditation of certifying agents.

Table 1 includes estimated direct costs of accreditation and certification for the first proposal and this proposal; the fees in this proposal are discussed in prior sections of this RFA. The fee provisions in this proposal have been changed significantly, due in large part to comments received regarding the first proposal.

In overall design, the first proposal is similar to this proposal. USDA would accredit certifying agents who would in turn certify producers and handlers. USDA proposed to charge certifying agents a \$640 application fee, costs for a site evaluation fee that were estimated at \$3,500, and a \$2,000 administrative fee. Producers would be charged a \$50 USDA fee in addition to the fees imposed by the certifying agent. Handlers would be charged a \$500 USDA fee on top of the certifying agent's fees. The fee structure was intended to recover the full costs of operating the National Organic Program, which was estimated at \$1 million annually. Producers with \$5,000 or less in annual gross sales of agricultural products and handlers with annual gross sales of less than \$5,000 were exempt from certification as provided for in the OFPA.

The OFPA permitted but did not obligate USDA to charge fees. The first proposal sought to set fees to recover the full costs of the National Organic Program. Public comment generally stressed that the fees were too high. Most certifying agents have operated without third party accreditation. Thus, USDA fees were a substantial increase in the costs of doing business for most certifiers. For producers the direct fee of \$50 was a 12 percent increase over the estimated average fee paid for certification. For certifying agents the \$500 fee would have been a 53 percent increase over estimated average certification fees. To the extent the program raised certifying agent costs, these costs would have been passed through to producers and handlers. Commenters stated that many certifying agents had few clients and to pass through the estimated direct costs of accreditation (\$6,140) would make the costs of certification higher than producers could afford.

Comments were received opposing fee provisions in the first proposal. Most of these commenters expressed the belief that the proposed fees would price small farmers, handlers, and certifying agents out of the organic industry. Many commenters stated that the proposed fees favored large farming operations and suggested a sliding scale fee system, rather than the flat fee system discussed in the first proposal, to

accommodate the economic needs of small farmers, handlers, and certifying agents. Most suggested that small farmers and processors be exempt from the payment of fees. A more comprehensive review of the comments appears in subpart G entitled "Administrative" of this proposal.

Additional comments were received that specifically referred to the section entitled "Regulatory Flexibility Act and Effects on Small Businesses" in the first proposal. Most of these commenters expressed the belief that costs were understated and benefits were overstated. Commenters thought the proposed fees were excessive, unacceptable, and burdensome and would price many small farmers, handlers, and certifying agents out of the organic industry. Some thought that this appeared to be the actual intent of the first proposal. They also supported a sliding scale fee system, rather than the flat fee system originally proposed. Some stated that the \$5,000 exemption level was much too low. Producers objected to having to pay the certification and inspection fees prior to knowing whether they would actually set a crop, if the crop would grow, or what percentage of the crop might be harvested.

Compared to this proposal, the first proposal would have been more costly to the organic industry in terms of direct costs for accreditation, and to producers and handlers in terms of direct fees and the costs which certifying agents would have attempted to pass through. However, the current proposal has not set fees at levels to recover all program costs and during an 18 month transition period will not require application fees or charge for hourly services. Costs that are not recovered through fees will be covered by appropriated funds, meaning that taxpayers at large will bear some of the costs of the proposed organic program. Thus, in terms of fees and other direct costs, the first proposal was more burdensome on the organic industry.

The first proposal also contained new information collection requirements, a description of those requirements, and an estimate of the annual economic burden on the organic industry. We received responses specifically referring to the information collection requirements of the first proposal. Among the comments made were that the requirements would be unaffordable by small businesses and that paperwork requirements should be kept small, simple, and to a bare minimum, especially for small producers.

Recordkeeping requirements for certifying agents in the first proposal that required certifying agents to maintain all records concerning their activities for 10 years have been changed to reduce the burden. Commenters expressed concern that this requirement was excessive and unnecessary. We agree and are instead proposing that there be three categories of records with retention periods: (1) Records created by certifying agents regarding applicants for certification and certified operations to be maintained 10 years, consistent with OFPA requirement for maintaining all records concerning activities of certifying agents; (2) records obtained from applicants for certification and certified operations to be maintained 5 years, the same as OFPA requirement for the retention of

records by certified operations; and (3) other records created or received by certifying agents to be maintained for five years.

Option 2: Fee per Certification Model

A fee per certification model was considered but not used. This model would have based accreditation fees on the numbers of farmers and handlers certified. Specifically, certifying agents would pay a fee to USDA for each certification performed. The smallest one-half of certifying agents, who certify about 10 percent of organic operations, would pay about 10 percent of the estimated costs associated with accreditation. The largest 10 percent of certifying agents, who certify about 45 percent of organic operations, would pay about 45 percent of accreditation costs. The remaining 40 percent of certifying agents in the middle would pay 45 percent of the costs. The fee per certification would be fixed, regardless of the size of the operation being certified. This feature has the potential to create a barrier to market access for the smaller operations. Certifying agents who charge farmers and handlers for certification based on size and scope of the operation would maximize their profits by certifying only the larger farmers and handlers from whom they would realize a higher return. If certifying agents were to discriminate in this manner in favor of larger operations, smaller farmers and handlers would find the certification services available to them to be relatively limited and possibly more expensive than under the fee for direct services model that includes a variable fee for site visits. A fixed fee per certification also would not take into account, in the distribution of costs, the large difference in size between processors and primary producers. Processors are generally much larger than primary producers in terms of both total output and total revenue.

Option 3: Exemption of Small Certifying Agents From Accreditation

Small certifying agents (those with annual revenues of \$25,000 or less) may not have the resources to meet all of the requirements of the rule, such as accreditation fees, administrative and personnel requirements, and conflict of interest restrictions, based on their current structure and revenues. Therefore, exempting the smallest certifying agents from the accreditation requirement, similar to small producers being exempt from certification requirements, could mitigate any potential adverse impact of the rule on this group. This option, however, would require a legislative amendment to the OFPA.

The exemption of the smaller certifying agents from accreditation would carry with it many of the limitations resulting from the absence of Federal oversight. International trade would likely be limited to products certified by accredited certifying agents. Protecting domestic consumers from inappropriate organic claims on the labels of products certified by exempt certifying agents would likely lead to greater confusion over labels in the marketplace. Federal enforcement agencies such as the FDA, the ATF, and FSIS might wish to distinguish accredited certifying agents from those

certifying agents who are exempt, perhaps by requiring accredited certifying agents' clients to include the USDA seal on their product labels.

One of the purposes of the OFPA described in the statute is to assure consumers that organically produced products meet a consistent standard. Without Federal oversight of certifying agents, it would be difficult to ensure that one national standard of production and handling for agricultural products would be employed. The result could be the continuation of reciprocity agreements between small, exempt certifying agents and large accredited ones. This could result in a cost for small entities, while providing less benefit to certified producers and handlers than would be provided them by accreditation of all certifying agents.

We request comments from all interested parties, particularly small businesses, as to whether a small certifier exemption would be beneficial or practical given the constraints explained in this option.

Option 4: This Proposal

The new proposal includes provisions that will mitigate the impact of the National Organic Program, especially for small businesses. Fixed administration fees for producers, handlers and certification agents have been eliminated. The fixed application fee for accreditation also has been eliminated. This will positively affect small producers and handlers because fixed fees expend a larger percentage of a smaller operation's total revenue.

As indicated earlier in this discussion, certifying agent evaluation fees would reflect actual costs for the time and travel required to do the evaluation. It is anticipated that smaller certification agents would benefit because they are small and less complex than larger certification agents. The proposed accreditation costs would be proportional to the actual time required to perform the service. Several small operations could be grouped by area to reduce travel expenses of the evaluators.

The new labeling requirements that allow the use of a certification agent's seal on the principal display panel and on the information panel of processed product labels also may benefit small operations. Certification agents that have an established consumer base may benefit by displaying their identifying seal. Small certification agents, whose clients more likely produce ingredients for processed products, could also be identified and thus share in this benefit. Certification agents also may wish to expand their operation by offering verification of truthful labeling claims which will be allowed under this proposal.

This proposal has three elements of flexibility that are advantageous to small entities: performance-based production and handling standards and certifying agent requirements; production and handling standards that contain a range of allowable practices; and temporary variances.

The standards in this proposal are performance standards based on the results of a management system, rather than prescriptive or design standards that prescribe specific technology or a precise

procedure for compliance. Performance standards allow for flexibility in compliance, which is especially important to organic farmers, handlers and certifying agents with limited resources. Performance standards promote innovation and the development of new technologies which would help the industry as a whole be more efficient. Finally, they provide a less costly means of compliance than design standards. Small entities, in particular, benefit because compliance with performance standards allows for the adaptation of existing systems without costly capital investment.

This proposal allows for flexibility by providing a range of production and handling practices that can be used to maintain the organic integrity of the operation. The use of an allowed practice or substance must be described in the organic plan as a record for consideration by the certifying agent during a certification review. The proposal provides temporary variances in the case of natural disasters, damage from wind, floods and the like, and for research trials. The benefit of variances is that a producer or handler would not lose its investment in an organic operation because of certain conditions that are beyond the producer or handler's control. Variances also enhance performance standards by allowing additional innovation and experimentation. This is especially important to producers and handlers who depend on the organic price premium.

Conclusion

USDA has identified the entities that may be affected by this proposal and has analyzed the anticipated impacts of the proposal on them based on our knowledge of the industry and limited data. We have drawn on industry studies, including studies completed since the first proposal was published in 1997, as well as information provided in comments on the first proposal. However, we lack data to thoroughly and quantitatively describe the existing organic industry and quantitatively analyze the effects of this proposal.

Whether using SBA's small business size standards by SIC or the alternative definitions created for this analysis, we believe that this proposal could have a significant impact on a substantial number of small businesses. Even with the flexibility proposed in the regulation and the expanded market opportunities brought about by implementation of the National Organic Program, some small certifying agents may choose not to become accredited to provide certifying services, and some small producers and handlers may choose not to continue being certified organic because the proposed fees would be passed down to them as certification fees. We invite comments about the expected benefits and costs to small entities as presented in this analysis. Specifically, we invite comments regarding the impact of the proposed National Organic Program on small certifying agents, producers, and handlers so that we might uncover potential unintended negative impacts on small entities.

The proposed structure of user fees outlined in this proposal attempts to minimize the burden of administrative costs which will be assumed by small-scale

organic certifying agents and the producers and handlers who use these certification services. Certifying agents already performing organic certification services in a State or private capacity on the date that the proposed national accreditation program for organic certification is implemented will not be required to pay the administrative costs of applying for initial national accreditation status; the administrative costs involved in evaluating the accreditation status of these agents will be absorbed by a portion of the National Organic Program operating budget appropriated by Congress. They will be required to pay travel expenses for the reviewers. New applicants seeking national accreditation for organic certification services will be charged a fee to cover the administrative costs of evaluating their suitability for accreditation, their application fees will be structured to reflect the actual hourly costs of having an AMS evaluator conduct a site visit (including travel time to and from the evaluator's duty station and per diem travel expenses). The departures from the first proposal—which would have imposed a uniform flat fee on all applicants for national accreditation—along with the adoption of an application fee structure which attempts to relate the imposition of fees to the actual costs involved in administering the national accreditation program, should contribute to a less burdensome and more equitable distribution of administrative costs across all segments of the organic industry.

Appendix D—Paperwork Reduction Act of 1995

The Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506 and 3507) is designed to minimize the burden of reporting and recordkeeping (information collection requirements) required by Federal regulations on individuals, businesses, other private institutions, and State and local governments. The burden is an estimate of the amount of time and the cost required of program participants to fulfill the information collection requirements.

Information collection requirements must have Office of Management and Budget (OMB) review and approval before they can become effective. They must also be made available for public comment, and the comments become part of the public record. This notice requests comments on the proposed information collection requirements of this proposal.

Title: National Organic Program.

OMB Number: New collection.

Expiration Date of Approval: Three years from date of approval.

Type of Request: New.

Abstract: The Organic Foods Production Act (OFPA) of 1990 mandates that the Secretary develop a National Organic Program (NOP) to accredit eligible State program's governing State officials or private persons as certifying agents who would certify producers or handlers of agricultural products that have been produced using organic methods as provided for in the OFPA. This regulation is proposed: (1) To establish national standards governing the marketing of certain agricultural products as

organically produced products; (2) to assure consumers that organically produced products meet a consistent standard; and (3) to facilitate interstate commerce in fresh and processed food that is organically produced.

The OFPA was requested by the organic community because of problems encountered in the marketing of organic products. First, there was fraudulent use of the term, "organic," resulting in the mislabeling of products, caused in part because many consumers are willing to pay premium prices for organic foods. Second, there was a lack of uniformity in standards defining organic production, causing trade disruption and confusion among buyers, sellers, and users of organic products. Third, there was constraint on market growth due to the prohibition on labeling meat and poultry products as organic. After implementation of the NOP, any agricultural product labeled "organic" will have to be from a production or handling operation that is certified by a certifying agent who is accredited by the U.S. Department of Agriculture (USDA).

A proposed rule to implement the OFPA was published in December 1997. It contained information collection requirements, an estimate of the annual economic burden on the organic industry, and a request for comments about the burden. A few general comments were received about the burden and they were considered when this proposal was prepared. Also taken into account was other information about existing industry practices and documents, the Initial Regulatory Flexibility Analysis that is discussed in the section entitled "Regulatory Flexibility Act and the Effects on Small Businesses," and the Regulatory Impact Assessment (RIA) that is discussed in the section entitled "Executive Order 12866." The numbers of entities affected by this proposal are estimated in the RIA. The RIA is attached as an appendix to this proposal.

Reporting and recordkeeping are essential to the integrity of the organic certification system. They create a paper trail that is a critical element in carrying out the mandate of the OFPA. They serve the Agency mission, program objectives, and management needs by providing information on the efficiency and effectiveness of the program. The information affects decisions because it is the basis for evaluating compliance with the OFPA and the regulations, for administering the program, for management decisions and planning, and for establishing the cost of the program. It supports administrative and regulatory actions in response to noncompliance with the OFPA and the regulations.

In general, the information collected will be used by USDA, State program's governing State officials, and certifying agents. It will be created and submitted by State and foreign program officials, peer review panel members, accredited certifying agents, organic inspectors, certified organic producers and handlers, those seeking accreditation or certification, and parties interested in changing the National List. Additionally, it will necessitate that all of these entities have procedures and space for recordkeeping.

The burden on each entity is discussed below. One major estimate made about each entity is the number of entities likely to participate in the NOP. The information collection burden attempts to incorporate the burden that will be in addition to the burden that current organic marketers have with the burden required of new entrants into the field.

USDA. USDA will be the accrediting authority. USDA will accredit domestic and foreign certifying agents who will certify domestic and foreign organic producers and handlers, using information from the agents documenting their business operations and program expertise. USDA will also permit State program's governing State officials to establish their own organic certification programs after the programs are approved by the Secretary, using information from the States documenting their ability to operate such programs and showing that such programs meet the requirements of the OFPA and the regulations.

States. State program's governing State officials may operate their own organic certification programs. State officials will obtain the Secretary's approval of their programs by submitting information to USDA documenting their ability to operate such programs and showing that such programs meet the requirements of the OFPA and the regulations. More than half of the States currently have some standards governing the production, handling, or labeling of organic food and 13 States have organic certifying programs. These programs require reporting and recordkeeping burdens similar to those required by the NOP. It is unknown at this time how many States, if any, will establish their own organic certification programs pursuant to the OFPA and the regulations. *Estimates:* 13 States will operate their own certification programs. The annual burden for each State will be an average of 52,308 hours or if calculated at a rate of \$27 per hour, (rounded up to the next dollar), it would be \$1,413.

Peer review panels. Panels will assist the Agricultural Marketing Service (AMS) Administrator in evaluating applicants for accreditation as certifying agents. Individuals will apply to USDA for membership in a pool from which the panels are selected, submitting to USDA information documenting their qualifications to conduct such reviews. This will be a new burden for those serving on the panels. *Estimates:* 40 people will participate in peer review panels. The annual burden for each panel member will be an average of 10 hours or if calculated at and \$27 per hour, it would be \$270.

Certifying agents. Certifying agents may be State program's governing State officials, private entities, or foreign entities who are accredited by USDA to certify domestic and foreign producers and handlers as organic in accordance with the OFPA and the regulations. Each entity wanting to be an agent will seek accreditation from USDA, submitting information documenting its business operations and program expertise. Accredited agents will determine if a producer or handler meets organic requirements, using detailed information from the operation documenting its specific

practices and on-site inspection reports from organic inspectors. *Estimates:* 59 entities are expected to apply for certification (13 State programs, 36 private entities, 10 foreign entities). The annual burden for each State program will be an average of 695,428 hours or if calculated at \$18,778. The annual burden for each private or foreign entity will be 699,678 hours or \$27 per hour (rounded up to the next dollar) it would be \$18,893.

Administrative costs for reporting, disclosure of information, and recordkeeping are expected to vary among certifying agents. Entities which begin their activities only after the national program is implemented would be expected to incur the greatest cost as they set up an operation that conforms to the OFPA and the regulations. For agents who are currently active in the organic industry, follow ISO guidelines, and already perform many of these administrative functions, costs will vary depending upon the extent to which their current practices are different from requirements in the OFPA and the regulations. Agents will be expected to provide the public with information concerning their clients. Efforts were made to incorporate existing industry practices and documents into this proposal. A list of several proposed administrative requirements and the probable resources required for compliance is included in the Regulatory Impact Assessment.

When an entity applies for accreditation as a certifying agent, it must provide a copy of its procedures for complying with recordkeeping requirements (§ 205.504(b)(3)). Once certified, agents will have to make their records available for inspection and copying by authorized representatives of the Secretary (§ 205.501(a)(9)). USDA will charge certifying agents for the time required to do these document reviews. Audits will require less time if the documents are well organized and centrally located, than if they are in disarray and in several locations. Certifying agents will have control over these conditions, but making documents accessible to the public may bring about a substantial change in the way some agents currently operate.

Recordkeeping requirements for certifying agents in the first proposal were changed to reduce the burden. They required certifying agents to maintain all records concerning their activities for 10 years. Commenters expressed concern that this requirement was excessive and unnecessary. We agree and are instead proposing three categories of records with varying retention periods: (1) records created by certifying agents regarding applicants for certification and certified operations, maintain 10 years, consistent with OFPA's requirement for maintaining all records concerning activities of certifying agents; (2) records obtained from applicants for certification and certified operations, maintain 5 years, the same as OFPA's requirement for the retention of records by certified operations; and (3) records created or received by certifying agents regarding accreditation, maintain 5 years, consistent with OFPA's requirement for renewal of agent's accreditation (§ 205.510(b)).

Residue testing requirements in the first proposal were changed to reduce the burden. They required certifying agents to undertake

residue testing every 5 years to determine if products from certified operations contained a detectable residue level of a prohibited substance and to report such findings to appropriate authorities. Commenters expressed concern that the requirement was too costly. We agree and are instead proposing that the State program's governing State officials or certifying agents may conduct testing at their own expense only if they suspect a crop has come into contact with a prohibited substance. Test results must be submitted to the Administrator (§ 205.672(b)).

Organic inspectors. Inspectors will conduct on-site inspections for the certifying agents of each applicant for certification and annually of each certified operation. They will determine whether or not certification should continue and will report this finding to the certifying agent. Inspectors will be the agents themselves, employees of the agents, or individual contractors. We estimate that about half will be certifying agents and their employees and half will be individual contractors. Individuals who apply for positions as inspectors will submit to the agents information documenting their qualifications to conduct such inspections. *Estimates:* 293 inspectors (147 certifying agents and their employees, 146 individual contractors) will be used. The annual burden for each inspector will be an average of 48,304 hours or if calculated at \$27 per hour (rounded up to the next dollar), it would be \$1,305.

Producers and handlers. Producers and handlers, domestic and foreign, will apply to certifying agents for organic certification, to renew their certification, or to report changes in their practices, submitting to the agents detailed information documenting their specific practices. Producers include farmers, livestock and poultry producers, and wild crop harvesters. Handlers include those who transport or transform food and may include millers, bulk distributors, food manufacturers, processors, repackagers, or packers. Some handlers may be part of a retail operation that processes organic products in a location other than the premises of the retail outlet.

The OFPA requires certified operators to maintain their records for 5 years. *Estimates:* 19,300 total operators (14,153 certified and 5,147 exempt), including 17,150 producers (12,176 certified and 4,974 exempt) and 2,150 handlers (1,977 certified and 173 exempt). We do not have an estimate of the number of foreign producers and handlers that will apply for organic certification. The annual burden for each domestic operator will be: certified producer—average of 9,521 hours or if calculated at \$24 per hour, it would be \$229; certified handler—average of 49,521 hours or if calculated at \$24 per hour, it would be \$1,189; exempt/excluded operator—average of 0.5 hour or if calculated at \$24. per hour, it would be \$12.

The proposed regulation exempts certain operations from certification: (1) Producers and handlers whose gross agricultural income from organic sales totals \$5,000 or less annually; (2) handlers selling only agricultural products that contain less than 50 percent organic ingredients by total

weight of the finished product; (3) handlers that handle agricultural products that contain at least 50 percent organic ingredients and choose to use the word "organic" only on the information panel of a packaged product; and (4) handlers that are retail food establishments that handle organic food but do not process it. The proposed regulation also excludes certain operations from certification: (1) Handlers selling only agricultural products labeled as organic or made with organic ingredients that are enclosed in a container prior to being received, remain in the same container, and are not otherwise processed while in the control of the operation; and (2) handlers that are retail food establishments that process or prepare, on the premises, raw and ready-to-eat food from organic agricultural products.

Administrative costs for reporting and recordkeeping are expected to vary among certified operators. Entities which begin their activities only after the national program is implemented would be expected to incur the greatest cost as they set up an operation that conforms to the OFPA and the regulations. For operators who are currently active in the organic industry and already perform many

of these administrative functions, costs would vary depending upon the extent to which their current practices are different from requirements in the OFPA and the regulations. Efforts were made to incorporate existing industry practices and documents into this proposal. A list of several proposed administrative requirements and the probable resources required for compliance is included in the Regulatory Impact Assessment.

Research studies have indicated that operations using product labels containing the term "organic" handle an average of 19.5 labels annually, that there are about 16,000 products with the term organic on the label, and that the number of such products increased by 250 annually from 1994 through 1996. We estimate that by the year 2001, 17,000 products will be marketed with the term "organic" on the label. This proposal includes an estimate of the time needed to develop labels for products sold, labeled, or represented as "100 percent organic," "organic," "made with organic (specified ingredients)," or which use the term organic to modify an ingredient in the ingredients statement. Also included is the time spent

deciding about use of the USDA seal, a State emblem, or the seal, logo, or other identifying marks of a private certifying agent (§ 205.300–§ 205.310). Because the labeling requirements in this proposal are in addition to FDA and FSIS requirements, the burden measurement does not include the hours necessary to develop the entire label. For purposes of calculating the burden, it was estimated that each handler will develop 20 labels annually.

Interested parties. Any interested party may petition the NOSB for the purpose of having a substance evaluated for recommendation to the Secretary for inclusion on or deletion from the National List. *Estimates:* 25 interested parties may petition the NOSB. The annual burden for each interested party will be an average of 104 hours and \$2,496 (\$24 per hour).

Cost. The following table shows the salary rates used to calculate the cost of the burden. We believe the increased rates for this proposal over the first proposal are more realistic in terms of the responsibilities and requirements of each entity.

Estimated hourly rates	First proposal	This proposal
Certified and exempt operators, interested parties	\$10	\$24
State program's governing State officials, peer review panel members, certifying agents, organic inspectors	20	27

Annual Reporting and Recordkeeping Burden:

Estimated Number of Respondents: 19,730.

Total Annual Hours: 269,622.

Total Cost: \$6,780,348.

Comments. Comments are requested on these proposed information collection requirements. Comments are specifically invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of USDA, including whether the information would have practical utility; (2) the accuracy of USDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments should be submitted by the date stated in the section entitled **DATES** at the beginning of this proposal. However, they should be sent to (1) Office of Management and Budget, New Executive Office Building, 725 17th Street, NW, Room 725, Washington, D. C. 20503, Attention: Desk Officer, and to (2) Clearance Officer, USDA–OCIO, Room 404W, Jamie Whitten Building, STOP 7602, 1400 Independence Avenue, SW, Washington, D.C. 20250–7602. Additionally, comments may be sent by fax to (202) 690–4632 or submitted via the Internet through the National Organic Program's homepage at <http://www.ams.usda.gov/nop>.

Appendix E.—Executive Order 12988, Civil Justice Reform

Executive Order 12988, Civil Justice Reform, instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. The first proposal was reviewed under this Executive Order. No comments were received on that review and no additional related information has been obtained since then. This rule is not intended to have retroactive effect.

States and local jurisdictions are preempted under section 2115 of the OFPA (7 U.S.C. 6514) from creating programs of accreditation for private persons or State officials who want to become certifying agents of organic farms or handling operations. A governing State official would have to apply to the USDA to be accredited as a certifying agent, as described in section 2115(b) of the OFPA (7 U.S.C. 6514(b)). States also are preempted under sections 2104 through 2108 of the OFPA (7 U.S.C. 6503 through 6507) from creating certification programs to certify organic farms or handling operations unless the State programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA.

Pursuant to section 2108(b)(2) of the OFPA (7 U.S.C. 6507(b)(2)), a State organic certification program may contain additional requirements for the production and handling of organically produced agricultural products that are produced in the State, and for the certification of organic farm and handling operations located within the State, under certain circumstances. Such additional

requirements must: (a) Further the purposes of the OFPA; (b) not be inconsistent with the OFPA; (c) not be discriminatory towards agricultural commodities organically produced in other States; and (d) not be effective until approved by the Secretary.

Pursuant to section 2120(f) of the OFPA (7 U.S.C. 6519(f)), this proposal would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspections Act (21 U.S.C. 451 *et seq.*) or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*), concerning meat, poultry, and egg products, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 *et seq.*), nor the authority of the Administrator of the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 *et seq.*).

Section 2121 of the OFPA (7 U.S.C. 6520) provides for the Secretary to establish an expedited administrative appeals procedure under which persons may appeal an action of the Secretary, the applicable governing State official, or a certifying agent under this title that adversely affects such person or is inconsistent with the organic certification program established under this title. The Act also provides that the U.S. District Court for the district in which a person is located has jurisdiction to review the Secretary's decision.

Appendix—Executive Order 13132, Federalism

This proposal has been reviewed under Executive Order 13132, Federalism. This

Order requires that regulations that have federalism implications provide a federalism impact statement that: (1) Demonstrates the Agency consulted with the State and local officials before developing the proposed regulation, (2) summarizes State concerns, (3) provides the Agency's position supporting the need for the regulation, and, (4) describes how the concerns of State officials have been met. The Order indicates that where National standards are required by Federal statutes, Agencies shall consult with appropriate State and local officials in developing those standards. Further, Agencies are required to interpret Federal statutes to preempt State law only where the statute contains an express preemption provision. In such a case, any regulatory preemption of State law shall be restricted to the minimum necessary to meet the objectives of the statute.

The Organic Foods Production Act (OFPA) of 1990 (7 U.S.C. 6514) establishes national standards regarding the marketing of agricultural products as organically produced, assures consumers that organically produced products meet a consistent standard, and facilitates interstate commerce in fresh and processed food that is organically produced. In carrying out these purposes, the Act contemplates a significant role for the States and, in fact, envisions a partnership between the States and the Federal Government in meeting the requirements of the Statute. The Act specifies the State role and gives States recognition for their activities in organic agriculture in several ways. First, 7 CFR 6507 provides that States may establish a State organic certification program consistent with the national program. Second, these programs may contain more restrictive requirements than the National Organic Program established by the Secretary of Agriculture. To be more restrictive, State Organic programs are required to: further the purposes of the Act, be consistent with the Act, not discriminate against organic products of another State, and be approved by the Secretary. Third, States can choose to be accredited as certifying agents under the Act and carry out a State organic program. Fourth, the Act allows the States to determine the manner in which they choose to be involved in the organic program. States may choose to carry out the requirements of the Act by establishing a State program and becoming accredited as certifying agents, they may establish a State program and utilize private certifying agents to implement the program, or they may choose to utilize the national organic program as implemented by the Secretary.

In recognition of their role in carrying out the provisions of OFPA, the Department has reached out to States and actively sought their input throughout the entire process of developing the proposed organic rule. The Department drew extensively on the organic expertise of States and the organic industry by working closely with the National Organic Standards Board. The National Organic Standards Board, established under Section 2119 of the OFPA (7 CFR 6518), has provided a broad and inclusive forum for public participation in developing the recommendations and concepts that

underpin the proposed organic rule. Section 2104(c) of the OFPA (7 CFR 6503(c)) requires the Secretary to consult with the National Organic Standards Board in developing the organic program and the National List set forth in Section 2118 of the OFPA (7 CFR 6517).

The Secretary has received extensive input from the Board, interested persons, and the States regarding the establishment of the National Organic Program and this reproposal. The Board met 12 times before publication of the proposed rule on December 16, 1997, and has met five times during 1998 and 1999. States were invited to attend each of these meetings, and official State certifier representatives participated in Board deliberations in meetings held in July 1998 and July 1999. Public input sessions were held at each meeting to gather information from all interested persons, including State and local jurisdictions.

Section 2110(g) of the OFPA (7 U.S.C. 6509(g)) requires the Secretary to hold public hearings to gather information to guide development of standards for livestock products. Four hearings were held during 1994 in Washington, D.C.; Rosemont, IL; Denver, CO; and, Sacramento, CA. States were invited to participate in each of these hearings.

National Organic Program staff also received comments and consulted with States at public events. They made presentations, received comments, and consulted with States at local and regional organic conferences and workshops and at national and international organic and natural food shows.

Further, States were provided the opportunity to comment specifically on State issues at a National Organic Certifiers meeting held on July 21, 1995, to discuss accreditation issues; a meeting held on February 26, 1996, to discuss the role of States in the National Organic Program; and a February 1999 State Certifiers meeting to discuss State issues. Further, States were consulted in training sessions held for organic inspectors, as well as numerous question and answer sessions at speaking engagements of the Agricultural Marketing Service Administrator, the National Organic Program Program Manager, and the staff.

On publication of the first proposal on December 16, 1997, an announcement and information packet summarizing the first proposal were sent to over 1,000 interested parties, including State governors and State department of agriculture secretaries, commissioners, or directors. Subsequent to publication of the first proposal, State and local jurisdictions had the opportunity to provide input at four listening sessions held in February–March 1998 on the first proposal in Austin, TX; Ames, IA; Seattle, WA; and New Brunswick, NJ.

Finally, States had the opportunity to comment on the first proposal. More than 275,000 comments were received on the first proposal, including State commenters.

Through this extensive outreach and consultation process, States identified a number of issues with the first proposal. States expressed several specific concerns regarding accreditation requirements as they

affect State programs. These issues are described below, along with the Department's response in the reproposal.

(1) Under OFPA 2108 (7 CFR 6507), States may establish additional standards, approved by the Secretary. First, State commenters objected to the provision in the first proposal that would have prohibited States from requiring compliance with these additional standards as a condition for use of the organically produced State logo on products within the borders of such State. We agree with the commenters, as we did not intend to prohibit States from requiring that these more restrictive standards be met as a requirement to the State's logo on organically produced products. Accordingly, this proposal will permit States with more restrictive requirements approved by the Secretary and private certifiers certifying production and handling operations within these States to require that the State's more restrictive standards be met in order to use the State logo.

(2) The first proposal required annual organic inspector performance appraisal and annual program evaluations for certifying agents. State commenters objected that these requirements would duplicate State requirements. We do not intend for States to develop dual performance appraisal and program evaluation systems because we believe that programs already conducted by the States will meet the requirements of this proposal. These programs would be expected to conform with good management practices appropriate to an organization's size and structure. The questioned provisions have not been changed, but this proposal has been revised to clarify that the annual program evaluation can be conducted by the certifying agency staff, an auditing entity, or a consultant with appropriate expertise.

(3) The first proposal set forth confidentiality requirements for certifying agents. Commenters stated that these confidentiality requirements might conflict with State requirements for "open records." While we recognize this potential for conflicting requirements, records collected under the National Organic Program would be subject to the requirements of the Act. Where the Act and State requirements conflict, the Act would take precedence. There is no change to the confidentiality provision.

To clarify that authorized representatives of the Secretary or the applicable State program's governing State official may act on their behalf and must be given access to the records, this proposal adds the phrase "and their authorized representatives."

(4) This proposal will require that accredited certifying agents accept certification decisions made by another USDA-accredited certifying agent as equivalent. State commenters said that States should be able to control which certifying agents operate within their State.

The first proposal provided that accredited certifying agents accept the certification decisions made by another USDA-accredited certifying agent as equivalent to their own. Commenters representing State programs said that States should be able to control which certifying agents operate within their

State. Several commenters asked whether States with more restrictive standards could challenge certification decisions made by other accredited certifying agents. Under the Act, no organic product may be produced or handled to organic standards lower than the standards of the National Organic Program. A State Government may not prevent the marketing or sale within a given State of organic product produced in another State according to this proposal. While States may, with the approval of the Secretary, set more restrictive standards than the national organic standards for product produced or handled within their State, these requirements do not apply to products produced or handled in another State.

State programs approved by the Secretary will be required to treat all accredited certifying agents equally, and accredited certifying agents in one State cannot refuse to recognize another State's product certified to national standards. Accordingly, the requirement remains unchanged that a certifying agent accept certification decisions by another USDA-accredited certifying agent as equivalent.

(5) The first proposal required all certifying agents to submit documents and information on personnel, administrative, and financial policies and procedures to demonstrate organic expertise and ability to implement the National Organic Program. States commented that State certifying agents should not be required to submit such information, stating that these requirements should not apply to States with established personnel, administrative, and financial procedures. They also indicated that the review should be limited to organic program administration only, not to agencywide policies and procedures. We recognize that States have established personnel, administrative, and financial procedures and that these procedures would apply to State certifying agents. However, a stated purpose of the Act is establishment of national standards. Such standards should extend to uniform requirements for State and private certifying agents unless otherwise provided in the Act. Further, such information is necessary for the Administrator to make a determination on approval of an application for accreditation. Accordingly, the requirements for demonstrating organic expertise and ability to implement the National Organic Program remain the same for private and State certifying agents.

(6) The first proposal required a certifying agent to provide a description of procedures to prevent conflicts of interest and the identification of any food or agriculture-related business interests of all personnel intended to be used in the certifying operation. Commenters stated that existing State policies should be sufficient to prevent conflicts of interest for a State certifying agent and that lists of the business interests of all inspectors, program staff, and their families are not necessary.

We agree that existing State policies should be sufficient to prevent conflicts of interest but disagree that lists of the business interests of all inspectors, program staff, and their families are unnecessary. The Act (CFR 6515(h)) places responsibility for the

prevention of conflicts of interest with the certifying agent. However, the Department is responsible for ensuring that the certifying agent complies with that responsibility. The requirement to provide such a listing provides the Administrator information essential to identifying conflicts of interest. In addition, a stated purpose of the Act is to establish uniform national standards. These uniform standards should extend to uniform conflict of interest requirements for State and private certifying agents. The commenters have said that most States already have established conflict of interest policies and procedures so that the required information should be easily available for submission to the Administrator. Accordingly, no change has been made in this proposal.

Certification, the process of qualifying a producer or handler to sell agricultural products labeled as organic, raised several issues for States.

(1) The first proposal required an applicant for certification to supply required documentation to provide information necessary to allow a certifying agent to evaluate the application. State commenters suggested a provision be added to allow a certifying agent to require documentation from applicants in addition to that required by the first proposal.

A certifying agent can, if necessary, follow up on an initial application with requests for additional information, provided that information is needed to evaluate the application and determine compliance with the Act and regulations. We did not make the suggested change, as the existing language already allows the certifying agent to request additional information necessary to determine compliance with the Act and regulations.

(2) The first proposal laid out a certification program that provided for updates to a continuous organic certification. To meet continuation of certification requirements, the first proposal required an on-site inspection after receipt of the update to the application. A State certifying agent objected, saying that an on-site inspection after receipt of a renewal application is not consistent with current practice. Currently, on-site inspections conducted during the prior year are used to determine compliance with certification requirements at the time of renewal, along with a review of information submitted by the certified operation. The State certifying agent stated that an additional inspection at renewal time would not be useful if it was not an appropriate time to observe the certified unit in operation.

We disagree with the commenters, since certifiers are required to schedule on-site inspections when the certified operation can be observed for its compliance or ability to comply with the provisions of the National Organic Program. The initial certification, therefore, should have been granted when the on-site inspection verified compliance with certification requirements. The certified operation should be fulfilling its annual continuation of certification at a time when it can demonstrate its compliance with the Act.

States commented on several compliance issues included in the first proposal.

(1) The Administrator had sole authority to suspend or revoke the accreditation of certifying agents in the first proposal. Commenters indicated that State program's governing State officials should have the authority to suspend or revoke the accreditation of private certifying agents.

We agree that in a State with a program approved by the Secretary, the State program's governing State official should be authorized to suspend or revoke an accreditation granted by the Secretary to certifying agents operating within the State. We concur because of the Department's role in providing oversight to the State program, including its enforcement procedures, and have made that change in this proposal.

(2) Many commenters stated that the first proposal lacked adequate enforcement provisions, including enforcement by States with an approved State program.

We agree with the commenters that additional enforcement provisions are necessary for the National Organic Program. The following changes have been made in this proposal.

(a) As noted above, the State program's governing State official will now be authorized to suspend or revoke accreditation granted by the Secretary to certifying agents operating in the State.

(b) An enforcement proceeding brought by a State program's governing State official against a certified operation or certifying agent shall be appealable pursuant to the appeal procedures of the State program with no subsequent appeal rights to the Secretary.

States commented on several fees provisions in the first proposal.

(1) The first proposal required that payment of fees and charges to the Department be by certified check or money order. State commenters objected, saying it was insulting for USDA to require a State government agency to pay for its accreditation with a certified check.

Accordingly, we have removed this requirement, simply requiring that payments for fees and other charges for accreditation must be made payable to the Agricultural Marketing Service.

(2) Several State agencies objected to the fee provisions in the first proposal, expressing the belief that the proposed fees would price small producers and handlers out of the organic industry. Some State agencies commented that those small organic producers conducting their own on-farm handling would be forced out of the organic industry by the excessive handler fee and reporting burdens.

After review of the comments, we acknowledge that the fees charged in the first proposal may have discouraged industry growth and may not have facilitated interstate commerce of organic product. We have thus, modified the fee structure to reduce costs to all organic sectors and have removed the requirement that provided for payment of fees to the Department by certified production and handling operations. Instead, the Department will charge certifying agents only for fees and charges related to accreditation, with the balance of the costs of the program to be funded through appropriations.

(3) Some State certifying agents commented that State certifying agents should not be assessed accreditation fees. They stated that most State certifying agents could face large accreditation costs because they have many county or regional offices which would be considered subsidiaries, adding that these costs would be passed on to producers and handlers or paid with supplemental State funds. A few State certifying agents asserted that USDA should pay the States because of the State's contribution to the national program. One

State representative said that accreditation fees for State certifying agents should be less than for private certifying agents, as State certifying agents should involve less AMS review and oversight.

We disagree with those commenters who say that State certifying agents should not be assessed accreditation charges, be charged less, or be paid to certify production and handling operations. These actions would constitute unacceptable preferential treatment of State certifying agents to the detriment of private certifying agents. This

proposal will assess State certifying agents the same fees for accreditation under the same fee structure as private certifying agents.

We invite States and local jurisdictions to comment on the issues raised in this Federalism impact statement. We also encourage States and local jurisdictions to review and comment on this proposal as it relates to the operation of State organic programs.

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